



DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 1

[HHS-OS-2020-0008; HHS-OS-2021-0001]

RIN 0991-AC29

Department of Health and Human Services Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS or the Department) is issuing a final rule that repeals the regulations issued under two final rules: “Department of Health and Human Services Good Guidance Practices,” published in the *Federal Register* of December 7, 2020; and “Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions,” published in the *Federal Register* of January 14, 2021. This action removes HHS regulations regarding guidance, enforcement, and adjudication procedures.

DATES: This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the “Search” box and follow the prompts.

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SUPPLEMENTARY INFORMATION:

I. Overview

HHS is repealing two procedural rules that were issued in December 2020 and January 2021 to implement Executive orders (EOs) issued on October 9, 2019. One rule relates to guidance document procedures and the other relates to civil administrative enforcement and adjudication procedures (collectively, the Final Rules). The Department codified the Final Rules in 45 CFR part 1.

On January 20, 2021, President Biden, under a new Administration, revoked both EOs that served as the basis for the Final Rules and directed agencies to promptly take steps to rescind any rules and policies implementing or enforcing the revoked EOs, as appropriate and consistent with applicable law. Accordingly, the Department has reconsidered the Final Rules. We now conclude that they create unnecessary hurdles that hinder the Department's ability to issue guidance, bring enforcement actions, and take other appropriate actions that advance the Department's mission. The Department continues to abide by its longstanding commitment to follow applicable principles of due process and administrative law; however, upon further reflection, we now conclude that the Final Rules establish procedures well beyond anything required by applicable law. Moreover, in significantly burdening the Department, these procedures are inconsistent with the policies and goals of the current Administration to ensure that HHS can appropriately leverage administrative tools to protect and advance the public health and welfare. In addition, the Final Rules created a single set of procedures for guidance documents and civil enforcement for the entire Department, which we believe is contrary to the efficient and effective administration of the wide array of programs carried out by the Department, given the diversity of those programs.

For these reasons, we issued a notice of proposed rulemaking on October 19, 2021, to repeal the Final Rules. 86 FR 58042 (Oct. 20, 2021) (Repeal NPRM). As discussed in greater detail in the Repeal NPRM and in this document, and consistent with the President's January 20, 2021, directive, we are now repealing the Final Rules in their entirety.

II. History of the Rulemaking

On October 9, 2019, the White House issued two EOs: Executive Order 13891, “Promoting the Rule of Law Through Improved Agency Guidance Documents,” 84 FR 55235 (Oct. 15, 2019) (EO 13891), and Executive Order 13892, “Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication,” 84 FR 55239 (Oct. 15, 2019) (EO 13892). These EOs served as the basis for the Final Rules, which were promulgated by the Department in December 2020 and January 2021: “Department of Health and Human Services Good Guidance Practices,” 85 FR 78770 (Dec. 7, 2020) (the Guidance rule, effective January 6, 2021), and “Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions,” 86 FR 3010 (Jan. 14, 2021) (the Civil Enforcement rule, effective January 12, 2021). The Department codified the Final Rules collectively in 45 CFR part 1. Shortly after the rules became effective, on January 20, 2021, President Biden, under a new Administration, issued Executive Order 13992, which revoked both EOs that served as the basis for these rules and instructed agencies to rescind, “as appropriate and consistent with applicable law,” any rules that were based on the revoked EOs. 86 FR 7049 (Jan. 25, 2021). Consistent with that instruction, the Department carefully reconsidered the Final Rules and then published the Repeal NPRM explaining why it proposed to repeal the Final Rules. 86 FR 58042 (Oct. 20, 2021).

A. Revoked Executive Orders

EO 13891, “Promoting the Rule of Law Through Improved Agency Guidance Documents,” required agencies, among other things, to: treat guidance documents as non-binding both in law and in practice, except as incorporated into a contract; take public input on certain guidance documents into account; and make all guidance documents available on a single website. 84 FR 55235. EO 13892, “Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication,” imposed a number of procedural hurdles on agencies engaged in civil administrative enforcement or adjudication. 84 FR 55239. As noted, both EOs have since been revoked. 86 FR 7049.

However, prior to the revocation of these EOs, and consistent with the directive in EO 13891, the Department published the Guidance rule. Although EO 13892 did not require rulemaking, the Department also published a final rule to implement EO 13892, the Civil Enforcement rule.

B. Guidance rule.

On August 20, 2020, consistent with the requirements of EO 13891, HHS published a notice of proposed rulemaking entitled “Department of Health and Human Services Good Guidance Practices,” the stated purpose of which was to “promote the appropriate issuance and use of guidance documents” 85 FR 51396. The rule’s stated intent was to increase accountability, improve the fairness of guidance issued by the Department, guard against unlawful regulation through guidance, and safeguard the important principles underlying the United States administrative law system. *Id.*

The major provisions of the proposed Guidance rule were: (1) a requirement that each guidance document issued by the Department generally include certain information, including a statement that the guidance does not have the force and effect of law and is not binding unless specifically incorporated into a contract; (2) heightened procedures for “significant guidance documents,” including a period of notice and comment, a requirement for HHS Secretary (Secretary) approval on a non-delegable basis, and a requirement for submission to the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) for review under Executive Order 12866; (3) creation of a repository for all guidance documents along with a provision stating that guidance documents not in the repository are not effective and will be considered rescinded; and (4) procedures for the public to petition the Department to withdraw or modify any particular guidance document.

HHS proposed that its new requirements for guidance would apply to all components of the Department except for the Food and Drug Administration (FDA). 85 FR 51396. The preamble to the proposed Guidance rule explained that FDA already operates under a set of Good

Guidance Practice (GGP) regulations, *see* 21 CFR 10.115, as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 371(h); no other agency within HHS functions under a similar set of regulations or statutory provisions. 85 FR 51396. FDA's GGP regulations have been in effect for more than two decades. *See* 21 CFR 10.115. The preamble also explained that FDA would be proposing amendments to its GGP regulations to address EO 13891 separately. 85 FR 51396.

During the comment period for the notice of proposed rulemaking, the Department received nearly 90 comments on the proposed rule. 85 FR 78771. The comments are available at <https://www.regulations.gov/document/HHS-OS-2020-0008-0001/comment>.

The Department issued the Guidance rule on December 7, 2020. 85 FR 78770. In response to public comment and the Department's further consideration of the policies addressed in the rule, the Guidance rule made several changes to the proposed rule. First, in addition to the requirement in the proposed rule that the Secretary approve, on a non-delegable basis, all significant guidance documents, the final rule added the requirement that the Secretary approve, on a non-delegable basis, all *non*-significant guidance documents that the Secretary determines would implicate a policy matter of priority to the Secretary, potentially create a serious inconsistency, or otherwise interfere with an action taken or planned by another HHS agency or the Office of the Secretary. *Id.* at 78786.

Second, the Guidance rule added more detail on what information the Department needs to provide when responding to a petition to amend or withdraw guidance, including a statement on whether the Department agrees or disagrees with the petition and its rationale. 85 FR 78787.

Third, although FDA had been excluded from the scope of the HHS proposed Guidance rule, the final Guidance rule included FDA within its scope. 85 FR 78785. The preamble to the final Guidance rule explained that one commenter had urged HHS to amend FDA's GGP regulations to be consistent with the requirements in the HHS Guidance rule. 85 FR 78771. HHS agreed with this comment, and then explained that, because the FDA regulations had not

yet been amended to address EO 13891, FDA would be included in the Guidance rule until the Secretary issued a final rule amending FDA’s separate GGP regulations. *Id.*¹ The Department did not reopen the comment period to invite comments on the inclusion of FDA within its scope.

The Department codified the Guidance rule in 45 CFR 1.1 through 1.5.

C. Civil Enforcement rule.

On January 14, 2021, HHS issued a final rule entitled “Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions.” 86 FR 3010 (Jan. 14, 2021). The Civil Enforcement rule, which was issued as a procedural rule without notice-and-comment rulemaking, stated that it was intended to provide regulated parties with greater transparency and fairness in administrative actions and to be consistent with the requirements of EO 13892. 86 FR 3010. The Department stated that “[t]he rule is designed to ensure accountability, fairness of how the Department uses guidance, proper use of guidance documents, and opportunities for third parties to be heard, and to safeguard the important principles underlying the United States administrative law system.” 86 FR 3011.

The rule contains a number of provisions, including the following: (1) a requirement that the agency avoid unfair surprise by only applying standards and practices in a civil enforcement action that have been publicly stated; (2) a requirement that, if the agency relies on a decision to assert new or expanded claims of jurisdiction, it must publish the initial decision in the *Federal Register* or the Department’s guidance repository before the conduct over which the jurisdiction is sought occurs; and (3) a requirement that the Department give parties—before the agency takes a civil enforcement action—written notice of its initial legal and factual determinations, an opportunity to respond in writing and in certain cases orally, and a written response to the affected entity (when timely requested).

¹ In fact, the Department did not issue a proposed or final rule to amend FDA’s GGP regulations to address EO 13891 before January 20, 2021, when EO 13891 was revoked.

The Department codified the Civil Enforcement rule in 45 CFR part 1, by revising §§ 1.1 and 1.2, and adding §§ 1.6 through 1.9.

D. Repeal NPRM

On October 19, 2021, HHS issued the Repeal NPRM proposing to repeal the Final Rules in their entirety. 86 FR 58042. The preamble explained that, after the Biden-Harris Administration revoked the EOs that served as the basis for these rules and directed agencies to promptly take steps to rescind any rules and policies implementing or enforcing the revoked EOs, as appropriate and consistent with applicable law, the Department reconsidered the Final Rules. That review led the Department to conclude that the Final Rules create unnecessary hurdles that hinder the Department’s ability to issue guidance, bring enforcement actions, and take other appropriate actions that advance the Department’s mission. The preamble further explained that these rules significantly burden the Department and are inconsistent with the policies and goals of the current Administration. We received approximately thirty comment submissions on the Repeal NPRM, which we have reviewed and considered. Our responses to the comments are discussed in Section IV.

III. Legal Authority

The legal authority for this final repeal rule is 5 U.S.C. 301. That provision states in relevant part that “[t]he head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.” The Guidance rule, the Civil Enforcement rule, and the Repeal NPRM relied on the same authority.

In addition, Congress’s grant of broad, discretionary rulemaking authority necessarily includes the authority not to promulgate — and therefore also to repeal — a proposed or final rule. *See Natural Res. Def. Council, Inc. v. Securities and Exchange Commission (SEC)*, 606 F.2d 1031, 1045 (D.C. Cir. 1979); *see also* 5 U.S.C. 551(5) (defining “rule making” to include

formulating, amending, and repealing a rule). In addition, “[t]he power to reconsider is inherent in the power to decide,” *Albertson v. Federal Communications Commission (FCC)*, 182 F.2d 397, 399 (1950), and, thus, “[a]dministrative agencies have an inherent authority to reconsider their own decisions.” *Trujillo v. Gen. Elec. Co.*, 621 F.2d 1084, 1086 (10th Cir. 1980).

IV. Discussion of Final Repeal Rule

This rule repeals the Final Rules, which had been codified in 45 CFR part 1. HHS will reserve 45 CFR part 1.

The thirty comments we received on the Repeal NPRM were mixed, but a substantial majority favored repeal. Commenters in favor of repeal consisted of non-profit policy and advocacy groups; a law school clinic; trade organizations; and an insurance company. Commenters in favor of retaining the Final Rules consisted of non-profit policy and advocacy groups; a law school clinic; trade associations; a state government agency; and individuals. This section summarizes and responds to the comments received and discusses the Department’s overall conclusions regarding issues related to repealing the Final Rules. In a few instances, the public comments offered were outside the scope of the proposed rule and will not be addressed in this preamble.

A. Comments on the Policy Basis for Repeal

1. *The Final Rules Run Counter to the Administration’s Goals of Advancing Public Health and Welfare.*

As discussed in the Repeal NPRM, the Biden-Harris Administration is committed to using available tools of Federal administrative agencies to, among other things: confront the urgent challenges facing the nation; equip executive departments with flexibility to use robust regulatory action to address national priorities; pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality; and protect and strengthen Medicaid and the Affordable Care Act (ACA) and make high-quality healthcare

accessible and affordable for every American.²

Many of the procedures in the Final Rules run counter to those goals. As the Repeal NPRM explained, the Final Rules were issued by the previous Administration to advance its policy goals, as reflected in Executive orders (EOs 13891 and 13892) issued under that Administration. The current Administration revoked both EOs 13891 and 13892 and directed agencies to take all necessary steps to halt implementation and enforcement of those EOs as appropriate and consistent with applicable law. *See* EO 13992. Accordingly, many procedural rules – like the Final Rules – that were issued by other departments and agencies under the previous Administration, have already been repealed.³

² See “Revocation of Certain Executive Orders Concerning Federal Regulation,” 86 FR 7049 (Jan. 25, 2021) (EO 13992); “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,” 86 FR 7009 (Jan. 25, 2021) (EO 13985); “Strengthening Medicaid and the Affordable Care Act,” 86 FR 7793 (Feb. 2, 2021) (EO 14009); “Continuing to Strengthen Americans’ Access to Affordable, Quality Health Coverage,” 87 FR 20689 (April 8, 2022) (EO 14070).

³ *See*

- Architectural and Transportation Barriers Compliance Board, “Procedures for Issuing Guidance Documents; Recission” 87 FR 5692 (Feb. 2, 2022) (rescinding rule creating internal procedural requirements on the issuance, public availability, and modification or withdrawal of guidance documents);
- Environmental Protection Agency, “On-Site Civil Inspection Procedures; Rescission,” 86 FR 74371 (Dec. 30, 2021) (rescinding rule on civil inspection procedures);
- National Endowment for the Arts final rule, “Procedures for Guidance Documents,” 86 FR 58809 (Oct. 25, 2021) (rescinding rule on issuing guidance);
- Department of Education final rule, “Rulemaking and Guidance Procedures,” 86 FR 53863 (Sept. 29, 2021) (rescinding rule on rulemaking and guidance procedures);
- Department of Justice interim final rule, “Processes and Procedures for Issuance and Use of Guidance Documents,” 86 FR 37674 (July 16, 2021) (revoking regulations regarding the issuance and use of guidance documents);
- Department of Housing and Urban Development final rule, “Implementing Executive Order 13992, Revocation of Certain Executive Orders Concerning Federal Regulation,” 86 FR 35391 (July 6, 2021) (removing regulations on guidance procedures);
- Department of Energy final rule, “Procedures for the Issuance of Guidance Documents,” 86 FR 29932 (June 4, 2021) (withdrawing final rule on issuing guidance);
- Federal Mediation and Conciliation Service final rule, “Recission of Federal Mediation and Conciliation Rule on Administrative Guidance,” 86 FR 29196 (June 1, 2021) (rescinding rule on guidance);
- Tennessee Valley Authority final rule, “Promoting the Rule of Law Through Improved Agency Guidance Regulations; Rescission,” 86 FR 28488 (May 27, 2021) (rescinding rule on guidance);
- Environmental Protection Agency final rule, “EPA Guidance; Administrative Procedures for Issuance and Public Petitions; Rescission,” 86 FR 26842 (May 18, 2021) (rescinding rule on guidance);
- National Endowment for the Humanities and National Foundation on the Arts and the Humanities final rule, “Processes and Procedures for Issuing Guidance Documents,” 86 FR 26184 (May 13, 2021) (rescinding rule on guidance);
- U.S. Office of Government Ethics final rule, “Removal of U.S. Office of Government Ethics Guidance Documents Regulations” 86 FR 25801 (May 11, 2021) (rescinding rule on guidance);
- Railroad Retirement Board final rule, “Guidance Documents,” 86 FR 22866 (Apr. 30, 2021) (rescinding rule on guidance);
- Social Security Administration final rule, “Rescission of Rules on Improved Agency Guidance Documents”

At least one commenter objected to the repeal of the recently promulgated rules because the process of promulgating and repealing rules in a short time period unnecessarily creates inconsistency and confusion and muddies the waters of the administrative world. We generally agree that the scenario of issuing rules that are then quickly repealed is regrettable. However, we disagree that the Final Rules should be retained merely for the sake of consistency, considering the substantial adverse impacts from these rules, as discussed in the Repeal NPRM, the comments, and this preamble. Given that both Final Rules involve matters relating to agency procedure and practice, the decision of one Administration to quickly issue procedural rules in the final weeks of its term to govern the operations of the next Administration can be seen as questionable and ill-timed. In sum, the Department now believes that the prior Administration's decision to issue these rulemakings was ill-advised, and it is necessary to repeal the resulting regulations, consistent with the revocation of similar rules by other departments and agencies.

2. *The Final Rules Impose Burdensome Standards and Procedures.*

As described in the Repeal NPRM, the Final Rules impose burdensome standards and procedures that interfere with HHS's ability to respond efficiently to public health matters. Contrary to the policy of the current Administration that agencies must be equipped with flexible and robust tools to address national priorities, including the COVID-19 pandemic, economic

86 FR 20631 (Apr. 21, 2021) (rescinding regulations on guidance);

- Department of Interior final rule, "Procedures for Issuing Guidance Documents," 86 FR 19786 (Apr. 15, 2021) (rescinding regulations on issuing guidance);
- Council on Environmental Quality final rule, "Guidance Document Procedures Rescission," 86 FR 19149 (Apr. 13, 2021) (rescinding regulations on issuing guidance);
- U.S. Agency for International Development final rule, "Procedures for the Review and Clearance of USAID's Guidance Documents; Rescission" 86 FR 18444 (Apr. 9, 2021) (rescinding regulations on issuing guidance);
- Department of Transportation final rule, "Administrative Rulemaking, Guidance, and Enforcement Procedures," 86 FR 17292 (Apr. 2, 2021) (removing regulations regarding issuing guidance and conducting enforcement actions, among other things);
- Pension Benefit Guaranty Corporation final rule, "Rescission of Pension Benefit Guaranty Corporation Rule on Guidance," 86 FR 17066 (Apr. 1, 2021) (rescinding rule on issuing guidance);
- Department of Labor final rule, "Rescission of Department of Labor Rule on Guidance," 86 FR 7237 (Jan. 27, 2021) (rescinding rule on issuing guidance).

We note that most of these rules were issued and repealed without engaging in notice-and-comment proceedings.

recovery, racial justice, and climate change, *see* EO 13992, these rules inappropriately constrict and impede the Department's ability to: (1) efficiently direct and operate in the interest of public health; (2) quickly communicate its regulatory interpretations, policies, and recommendations, such as by unduly extending the time needed to promulgate significant guidance, and by limiting the use of tools such as circulars, bulletins, advisories, and other guidance documents; and (3) take swift enforcement action when appropriate.

Several commenters agreed with the Department's position on this issue as explained in the Repeal NPRM and reaffirmed that the Final Rules impose burdensome standards and procedures that interfere with HHS's ability to respond quickly and efficiently to public health matters. Commenters noted, for example, that the Guidance rule's notice-and-comment requirements at 45 CFR 1.3 were especially onerous and time-consuming and needlessly hinder HHS's ability to timely issue critical information on public health and HHS programs. This additional burden harms not only HHS programs, but also the people who rely on those programs. The commenters explained, for example, that robust, swift, efficient, and effective guidance can be a critical tool for conveying health and safety information to the public on accessing medical and preventive care services and communicating allocation of funding decisions to state health administrators. Commenters also noted that guidance is essential for Medicaid, Medicare, and ACA program enrollees, who often look to such guidance to explain complicated program rules and requirements. We discuss other comments regarding burdensome procedures in Sections IV.D. and E.

Although no commenter disputed that the Final Rules' requirements increase the burdens on the Department, several argued that these requirements were nonetheless necessary to increase transparency, accountability, and public participation in the regulatory process, and provide for a more robust and efficient administration. We disagree that the Final Rules are necessary to accomplish these ends. In the several months that these rules have been in effect, we have seen no evidence of benefit such as those suggested in comments from their operations.

Further, the comments supporting the original rules do not cite any evidence to support their opinions. As one commenter in favor of repeal explained, although the Final Rules stated that they were intended to enhance transparency, fairness, and stakeholder engagement, the Final Rules accomplish none of these goals. Instead, the Final Rules hinder the Department and frustrate its mission by creating new, confusing, and unnecessary bureaucratic inefficiencies that slow down or halt Department initiatives.

One commenter expressed concern that a repeal of the Guidance rule’s notice-and-comment provisions would deprive stakeholders⁴ of a framework for providing input on future Departmental guidance defined as significant under the rule. While the Department recognizes that repealing the Guidance rule will eliminate a Department-wide formal process for providing public input on such draft guidance, HHS agencies have adequate processes in place to obtain meaningful input from stakeholders on significant guidance without the Guidance rule’s cumbersome requirements. Moreover, we now conclude that any benefit derived from the ability to formally comment on guidance and providing the Department’s responses to comments—which, by operation of law, is non-binding and does not have the force and effect of an agency rule—is outweighed by the Department’s interest in quickly and responsively communicating current thinking on its rules and policies. Further, because compliance with these provisions diverts HHS labor to time-consuming comment analysis and response, eliminating these provisions would expedite the publication of guidance, enhance agency efficiency, and reduce administrative burden.⁵

3. *The Final Rules Harm Historically Underserved Constituencies.*

⁴ In the context of this document, “stakeholder” means anyone who may be affected or interested in a guidance document or civil enforcement action, including regulated entities, states, tribes, and local governments, groups working with beneficiaries, and individual members of the public.

⁵ As noted, FDA already operates under its own set of GGP regulations, *see* 21 CFR 10.115, as required by the FD&C Act, 21 U.S.C. 371(h), and these authorities require that certain categories of FDA guidance documents be implemented only after an opportunity for public comment is provided. This rulemaking does not intend to question or limit those authorities as applied specifically to FDA. As we discuss in Section IV.A.4.b. below, we do not believe it is efficient or effective for a Department as large and diverse as HHS to mandate a single set of procedures for guidance documents and civil enforcement for the entire Department.

As discussed in the Repeal NPRM and above, *see* Section IV.A.1., the Federal Government under the Biden-Harris Administration is pursuing a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. *See* EO 13985. Accordingly, the current Administration directed Federal agencies to recognize and work to redress inequities in their policies and programs that serve as barriers to equal opportunity. *Id.* The current Administration also aims to protect and strengthen Medicaid and the ACA and to make high-quality healthcare accessible and affordable for every American. EO 14009; EO 14070. To accomplish that policy goal, the current Administration directed HHS, among others, to examine its regulations and policies to better ensure that they help provide high quality and accessible health care for all, and do not undermine protections for people with pre-existing conditions under the ACA, reduce coverage under or otherwise undermine Medicaid or the ACA, or undermine the Health Insurance Exchanges or the individual, small group, or large group markets for health insurance in the United States.

As the Repeal NPRM further explained, both Final Rules disproportionately impact marginalized and historically underserved communities, because they make it harder for HHS agencies to take action to protect public health or remove bad actors from the market, which, in turn, harms those who need HHS services the most. In addition, because HHS frequently issues guidance to clarify policies and beneficiary protections under Medicaid, the additional regulatory hurdles and confusion created by the Guidance rule would delay the issuance of Medicaid guidance and thereby undermine HHS' goals of supporting program beneficiaries.

Several commenters agreed that the Guidance rule harms underserved groups by imposing burdensome requirements that impede HHS' ability to timely communicate important guidance on health programs. Commenters explained that Medicaid and other HHS programs that serve marginalized communities frequently rely on guidance to provide current information on program rules and requirements to program participants. Timely issuance of guidance is

therefore essential to ensure that participants receive the most up-to-date information and can access needed services. The Guidance rule, however, introduces unnecessary bureaucratic inefficiencies for guidance that slow down or prevent the publication of this information, to the potential detriment of program beneficiaries. Commenters noted that, during the COVID-19 pandemic, the Department has issued and continues to issue and update guidance on a range of topics affecting underserved communities, including vaccine coverage, healthcare safety net programs, and non-discrimination in the provision of health care among other topics. Subjecting these guidance documents to the Guidance rule's burdensome publication requirements has the potential to impede their release and harm individuals who rely on Medicaid and other HHS programs. Further, commenters noted that the automatic rescission provision of the guidance document repository, discussed in greater detail in Section IV.D.5 below, creates confusion for individuals seeking information about Medicaid, Medicare, and other HHS programs.

We agree with these comments. We believe that interested groups and individuals—in particular, beneficiaries of Medicaid, ACA, and other HHS programs relied upon by underserved communities and individuals—would be better served with a more nimble, less cumbersome, and clearer process that ensures the expeditious release of program information needed to access services. The Guidance rule frustrates this goal by imposing unnecessary, burdensome, and ambiguous requirements that slow down the guidance process and in turn delay dissemination of information needed to access Medicaid, ACA, and other HHS programs.

4. *The Final Rules Impede Department Flexibility.*

- a. Codified, binding rules are too rigid for Department-wide implementation, and the Final Rules open the door to opportunistic litigation.

In addition to HHS's concerns about the substance of the Final Rules, HHS also has concerns about the procedural choice to implement them through binding, Department-wide regulations. Binding regulations have drawbacks that, in HHS's view, make them ill-suited for the Department-wide procedures at issue here.

First, binding regulations can be inflexible. This inflexibility raises several concerns regarding the ability to adapt to different circumstances. For example, the Final Rules impact a wide range of agency actions that come under the umbrella of guidance and civil enforcement proceedings, and the range and diversity of these types of actions are shaped by the various missions and underlying authorities of each of HHS's individual agencies. When HHS hastily issued these rules, it did not—and could not—fully consider all of these actions and how the rules would affect them. For example, HHS did not consider how the Guidance rule's procedures could slow down the work of other agencies, such as when HHS seeks to issue joint guidance, as it has with the Department of Labor and the Department of the Treasury. Similarly, the Civil Enforcement rule imposed a formalized system of written communication regarding a potential issue of non-compliance, without adequately considering that HHS agencies already have procedures and practices in place that allow for other options, such as in-person discussions, depending on the context. Since issuing these binding regulations, the Department has been tethered to specific procedures and cannot adjust its procedures as appropriate in specific circumstances.

Codified requirements also make it more difficult for the Department to adapt its procedures over time. The Department recognizes that a variety of factors—such as changing circumstances, new priorities, public health emergencies, input from interested parties, new technology, changes in applicable legal precedent, and agency experience—may require HHS to modify its procedures. It is unrealistic to expect any set of procedures to fully account for the range of circumstances that may confront HHS now or in the future. Codification of regulations, however, makes the modification process more burdensome. The issue is particularly pronounced considering the decision to issue the Guidance rule through notice-and-comment rulemaking, which may make revisions and updates more cumbersome. Indeed, most of the other Federal departments and agencies, in issuing (and repealing) similar regulations under the prior Administration, did not use notice-and-comment rulemaking procedures. *See* Section

IV.A.1. n 3.

This inflexibility is especially problematic when the Department does not necessarily know, at least without more experience, which procedures would most effectively achieve its goals. For example, the Guidance rule mandates the use of a centralized HHS guidance repository, but many commenters were critical of its current functionality. Commenters explained that the search function often failed to find the most relevant documents and instead retrieved irrelevant ones. Some commenters suggested that the search function may be improved by separating the database by HHS agency to help ensure more focused responses to queries. HHS explained in the Repeal NPRM that, while it proposed to repeal the regulation governing the guidance document repository, HHS intended to retain the repository itself (absent the automatic rescission provision) with changes to improve its functionality. Repealing the regulation will facilitate making improvements to the functionality of the centralized repository to address the problems related to its initial set-up, and to adapt to technological changes going forward—without considering whether those changes require amending the regulation.

Second, HHS no longer believes it is appropriate to create an opportunity for lawsuits on these procedural rules, in which a litigant may cite to binding regulations to allege a cause of action against the Department. As noted elsewhere in this preamble, the procedural requirements in the Guidance and Civil Enforcement rules are self-imposed and go beyond the requirements in preexisting law, such as the Administrative Procedure Act (APA). Both because these rules establish new procedural requirements and because many provisions in the rules are opaque and susceptible to multiple interpretations, HHS is concerned about the risk of opportunistic litigation here, which can consume time and resources even when the litigation lacks merit. In addition, other Federal departments and agencies under the previous Administration, in issuing similar procedural rules, expressly provided that the regulations were “not intended to, and do[] not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its agencies or other entities, its officers or employees, or any

other person.” *See, e.g.*, 84 FR 71729 (Dec. 27, 2019). HHS, however, did not include such a provision in the Final Rules. Thus, it is possible that, if the Final Rules are not repealed, litigants will attempt to sue HHS based on non-compliance with these procedural regulations.

Expending resources on this type of litigation is wasteful: even if the Department had no concerns with the substance of the procedures (which it does, as explained elsewhere), HHS believes that its resources are far better spent on public health initiatives that can improve the health and safety of Americans than on defending challenges concerning compliance with self-imposed procedures.

b. The Final Rules are not tailored to the various HHS agencies.

Another concerning aspect of the Final Rules is their establishment of a single set of procedures for guidance documents and civil enforcement for the entire Department, which is incompatible with the efficient and effective administration of a Department as large and diverse as HHS. The Department’s mission is to enhance the health and well-being of all Americans, and it accomplishes that mission through the work of many individual agencies, including the Administration for Children and Families (ACF), the Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), FDA, the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), the National Institutes of Health (NIH), and the Office for Civil Rights (OCR). Each of HHS’s agencies plays a critical role in protecting and advancing public health by, for example, confronting the COVID-19 pandemic; administering and overseeing the Medicaid and Medicare programs and ACA Exchanges; providing Federal health services to more than two million American Indians and Alaska Natives; taking action to protect consumers from unapproved, misbranded, or adulterated human or animal medical products or tobacco products; investigating, detaining, and recalling contaminated foods; addressing medical product shortages; enforcing age-restrictions or other controls around access to certain regulated products; and quickly distributing grant funds that help marginalized populations, low-income

families, elderly Americans, Indian tribes, and persons with disabilities to receive key resources, especially during the COVID-19 pandemic. Each agency within HHS serves the overall mission but does so in unique ways, often addressing different stakeholders and using specialized regulatory tools.

Several commenters confirmed that they share these concerns regarding the imposition of inflexible requirements on all HHS agencies. Regarding the Guidance rule, one commenter explained that the uniform requirements imposed by the rule primarily serve to make the issuance of guidance more cumbersome and less responsive to the needs of the communities who benefit from HHS programs. Another comment explained that burdensome, one-size fits-all procedural requirements that the Guidance rule imposes on CMS are the epitome of practices that present unnecessary barriers to individuals and families seeking Medicaid coverage. Regarding the Civil Enforcement rule, a commenter explained that application of the new enforcement requirements to all HHS agencies may cause confusion as various agencies under the HHS umbrella each already have procedural regulations, some of which have been specifically designed to govern a particular type of proceeding. We agree with these comments and find that they raise valid concerns supporting repeal.

In contrast, one commenter asserted that the Final Rules did not establish a single set of procedures for the Department; instead, the Final Rules merely expressed broad principles—consistent with the APA and due process—that allow HHS agencies to retain discretion to devise procedures for carrying out their statutory mandates that are consistent with those broad principles. Another commenter similarly claimed that the Repeal NPRM erred in asserting that the notice requirements in the Civil Enforcement rule conflict with or undermine preexisting procedures. We disagree with both comments because the Final Rules created actual conflicts and inconsistencies with preexisting agency procedures. For example, with respect to procedures for issuing guidance, the FD&C Act and the Guidance rule provide for different circumstances when guidance will be subject to prior notice and comment and different criteria for a guidance

to be exempt from prior notice and comment. *Compare* 21 U.S.C. 371(h)(1)(C)(1) and 45 CFR 1.3(b). While the FD&C Act provides for an appeals mechanism when FDA employees are not using guidance in accordance with the FD&C Act, the Guidance rule provided that this should be addressed in a petition. *Compare* 21 U.S.C. 371(h)(4) and 45 CFR 1.5(a)(2). For petitions, the Guidance rule specifies one set of requirements regarding their submission, response time, and substantive review and response, 45 CFR 1.5, while FDA regulations provide different governing requirements in each of those areas for its citizen petitions, 21 CFR 10.20 and 10.30(b) (submission), (e)(2) & (4) (response time), and (e)(1) & (3) and (h) (substantive review and response).

FDA also has regulations governing various types of adjudicatory hearings, *see* 21 CFR parts 12, 16, and 17, which conflict with the Civil Enforcement rule. For example, the Civil Enforcement rule provides for a series of limitations on the grounds for civil enforcement actions, 45 CFR 1.6 through 1.8, which are not consistent with FDA's governing regulations for civil money penalty (CMP) proceedings. 21 CFR 17.1, 17.5. FDA's CMP regulations establish an adjudicatory process that is similar to the Federal process for civil adjudication, with a complaint, answer, motions, and hearing. *See, e.g.,* 21 CFR 17.5, 17.9. In contrast, the Civil Enforcement rule requires that, after the affected entity responds to the initial notice, HHS must respond to the affected entity in writing, articulating the "basis for its final decision." 45 CFR 1.9. That requirement makes no sense in the context of 21 CFR part 17. Having two sets of regulations governing FDA guidance practices, citizen petitions related to FDA guidance documents, and CMP proceedings creates practical difficulties and confusion.

Other provisions that do not directly conflict with existing processes create additional layers of process. For example, while the FD&C Act only requires uniform internal procedures for the approval of guidance and provides discretion to the FDA to develop appropriate processes, the Guidance rule required Secretarial approval of significant guidance documents. *Compare* 21 U.S.C. 371(h)(1)(D)(2) and 45 CFR 1.3(b)(1). The FD&C Act requires FDA to

make its guidance documents available to the public, but the HHS Guidance rule required all guidance documents to be included in the repository and deemed guidance documents not included in the repository withdrawn. *Compare* 21 U.S.C. 371(h)(1)(A) and 45 CFR 1.4(a)(2).

Accordingly, the Department no longer believes that a one-size-fits-all approach to Department guidance or civil administrative enforcement is appropriate. The imposition of one set of requirements for HHS’ vastly different agencies hinders the agencies’ abilities to efficiently address public health issues, including but not limited to public health emergencies, and creates confusion.

5. *The Final Rules Divert Limited Department Resources.*

In the Repeal NPRM, the Department expressed the concern that the Final Rules divert agency resources without providing adequate compensating benefit, and that they are unnecessary. 86 FR 58049, 58051. Several commenters confirmed that, in their view, the Final Rules divert finite Department resources to unnecessary and unhelpful ends. The commenters were concerned that this diversion would delay Department activities that protect and advance the public health and welfare. For example, one comment asserted that the Final Rules make it harder for the Department to timely respond to emergencies, to address the glaring disparities in provision of services that have been highlighted during the COVID-19 pandemic, and to respond to and help shape the rapid changes in the healthcare delivery system. One comment disagreed and asserted that the Department’s statement in the Repeal NPRM—that “[h]aving a robust, efficient guidance system has been especially critical during the COVID-19 emergency”—“proves that the Rule does not impede the Department’s effective use of guidance.”

We agree with the comments expressing concern about the diversion of resources. Our experience with the Final Rules thus far is that they create unhelpful impediments to achieving Department goals, and addressing those impediments diverts resources from other Department priorities. The fact that the Department has devoted substantial resources to the COVID-19 crisis both before and after the Final Rules became effective does not undermine the

Department's position that the Final Rules impose unnecessary and burdensome requirements. For example, one comment explained that CMS guidance has played a critical role in addressing the COVID-19 pandemic and the Afghan mission. Although many of these important CMS guidance documents predate the Final Rules, those that followed the rules were required to adhere to the more onerous procedures of the Final Rules without any apparent benefits. We discuss below some examples in connection with consideration of specific provisions of the Final Rules. See Section IV.F.2.e.

In another example of resource diversion caused by the new procedures, the Department recently issued a response to a petition that purported to be submitted under the Guidance rule and that was addressed to HHS, CDC, and FDA. Attorneys from HHS, CDC, and FDA, as well as CDC and FDA subject matter experts, reviewed and deliberated on the petition. Ultimately, the Department concluded that petitioner had not properly invoked the Guidance rule procedures or appropriately included FDA in its request. Given the short timeline for responding to petitions under the Guidance rule, Departmental staff were forced to prioritize those deliberations over other, more significant matters.

In addition, as discussed above, because the Final Rules impose rigid requirements and do not disclaim any right of action based on them, it is possible that litigants will sue HHS based on non-compliance with these procedures. The Department has concluded that expending resources on litigating internal procedural rules is wasteful, and that its resources are far better spent on public health initiatives that can improve the health and safety of Americans than on defending challenges concerning compliance with self-imposed procedures.

B. Comments on Consideration of Purported Benefits of Final Rules.

Some commenters urged the Department to retain the Final Rules and identified several purported benefits. A few commenters asserted that the Final Rules helpfully clarify that guidance are simply non-binding, interpretive statements, consistent with the APA. One commenter asserted that Federal agencies have relied on guidance to reinterpret or expand the

law. Another commenter asserted that CMS had taken enforcement actions against it for violating policies based only on guidance, and therefore the Final Rules were appropriate to reaffirm basic principles of administrative law. Relatedly, another commenter urged the Department to provide greater clarity to the public on its rulemaking obligations related to Medicare pursuant to the Supreme Court's opinion in *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019). Another commenter asserted that the Final Rules provide notice and clarity by aggregating guidance documents in one central location. The same commenter suggested that the additional requirements for issuing significant guidance would help the Department screen for whether the guidance content would be more appropriately issued through rulemaking.

As discussed in more detail throughout this preamble, the Department has considered all comments on the purported benefits of the Final Rules and does not find that there are any significant benefits to retaining the Final Rules that outweigh the many detriments identified in the comments and summarized in the Repeal NPRM and in this preamble.

We disagree with the commenters who asserted that the Final Rules are necessary or appropriate to reaffirm the APA's principles of administrative law. As explained in the Repeal NPRM, "the APA governs agency conduct concerning guidance without the need for agency regulations." 86 FR 58049. Appropriate parameters and procedures for guidance issued by HHS agencies will remain in place after the Department repeals the Final Rules; and, repealing the Final Rules does not give an agency license to use guidance to establish or change policies where rulemaking is otherwise required, or to require outside parties to take or refrain from taking certain actions that are not addressed by statute or regulation. *See generally Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019) (finding, with respect to the Medicare program, that statements of policy that establish or change a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits must be promulgated through the notice-and-comment

rulemaking process). Accordingly, repealing the Final Rule will not transform guidance into binding rules with the force and effect of law.

The commenter who expressed disappointment that the Department has yet to apprise stakeholders of the agency's rulemaking obligations under section 1871 of the Social Security Act (SSA), as outlined in *Allina*, 139 S. Ct. at 1804, also requested that the Department provide greater clarity to the public on these rulemaking obligations, given the central role of the Medicare program in the Department's rulemaking and guidance procedures. We agree that the Medicare program is central to certain parts of the Department's rulemaking and guidance procedures. However, this specific request is outside of the scope of the Repeal NPRM, and therefore, the Department will take this request under advisement. In the interim, we invite those seeking information on CMS' rulemaking obligations under the Medicare Act to review the already-existing guidance available at <https://www.cms.gov/regulations-and-guidance/regulations-and-policies/cms-rulemaking>.

We disagree with another commenter's assertion that the process outlined for significant guidance in the Guidance rule is needed or helpful to screen for content that should be issued as a legislative rule. In particular, the comment opined that the Guidance rule's criteria for significant guidance documents will identify procedural defects in proposed guidance documents and thus effectively screen for guidance documents that are more likely to require notice and comment. The Guidance rule itself, however, made clear that its criteria for significant guidance documents does not necessarily correspond to the criteria for legislative rules. 85 FR 78776 (noting that to qualify as guidance, as opposed to a legislative rule, a document must reflect, implement, interpret, or describe a legal obligation imposed by a pre-existing, external source or advise the public prospectively of the way the agency intends to exercise a discretionary power).

With respect to the comment that repealing the Guidance rule erases the benefit of enhanced notice resulting from the aggregation of guidance documents in one central location, the Department plans to maintain a central guidance repository even after the Guidance rule is

repealed, without the problematic rescission requirement for documents not in the repository.

This topic is discussed in more detail in Section IV.D.5. below.

C. Comments on HHS Repealing the Final Rules in their Entirety

As the Department explained in the Repeal NPRM, the Final Rules: frustrate the Department's ability to efficiently direct and operate in the interest of public health; are inconsistent with the policies and goals of the current Administration; make Department operations more cumbersome and burdensome; impede the Department's ability to quickly communicate its regulatory interpretations, policies, and recommendations; and prevent the Department from using robust tools to protect and advance the public health and to promote the Department's mission. For those reasons, HHS proposed to repeal the Final Rules in their entirety and remove 45 CFR part 1.

The Repeal NPRM further explained that HHS had rejected the alternative approach of addressing these problems by revising the Final Rules. For the reason described in Section IV.A.4.b. above, it would be difficult to establish definitions, standard descriptors, policies, and procedures that are clear and workable across the Department's many components. Rather than codified, Department-wide procedures, the Department prefers a more flexible approach. With the repeal of the Final Rules, HHS agencies would be able to continue to follow or develop their own procedural policies, practices, and rules, consistent with applicable law and as appropriate to their context, and they would be able to update these over time and to address specific circumstances as warranted. *See* Section IV.A.4.b. This more decentralized approach is also consistent with the revocation of EO 13891, under which the previous Administration had taken a relatively centralized and standardized approach.

A few commenters objected to this aspect of our proposal, asserting that our concerns can be better addressed by fine-tuning the Final Rules rather than scrapping them entirely. One commenter, for example, asserted that the concerns noted by HHS in the Repeal NPRM (and raised by other comments submitted in earlier stages of the rulemaking) could be addressed by

targeted revisions to the Final Rules such as creating new exemptions for particular matters of concern.

We have considered these suggestions and reject the approach proposed by these commenters. We address these proposals in greater detail in Section IV.F.2.h. below, including the reasons for rejecting specific proposals for modifying the Final Rules. Here we explain, as a matter of policy, why we have chosen repeal over modification.

Although it may be possible, as the commenter asserts, to address *some* of the concerns noted by HHS in the Repeal NPRM through revisions and exemptions, HHS sees no value in doing so. Codifying procedural policies and practices as rules makes them more rigid. Updates and changes would become resource-intensive. None of this is desirable or necessary for these types of procedural policies and practices.

For example, the Guidance rule required Secretarial approval for guidance documents under certain circumstances. The Repeal NPRM expressed concern that this requirement could delay the issuance of these guidance documents by drawing on the Secretary's finite time and resources. A commenter asserted that the Secretarial approval requirement should be maintained to avoid a greater drain on the Secretary's time to fix guidance issued in error. We disagree with this comment and its underlying assumption. It is entirely speculative to assert that guidance will be issued in error if not done under the Secretary's signature. In any event, the Secretary is best positioned to determine how to appropriately allocate their time and resources, without having to publish a Federal Register document to codify a new set of procedures.

We are not convinced by the comments that there are benefits to mandating the procedures required by the Final Rules through codified regulations. As discussed elsewhere in this preamble, codification impedes the Department's flexibility to adapt its rules to different contexts across the broad spectrum of matters regulated by HHS agencies, opens the door to opportunistic litigation, and increases the burden and difficulty of adjusting and modernizing procedures. Improving processes less formally allows for efficient updates to respond to a

variety of factors, including changed circumstances, new priorities, public health emergencies, stakeholder input, and new technology.

D. Comments on Specific Issues Related to the Guidance Rule

1. *The Guidance Rule Created Administrative Hurdles that may Delay or Prevent Issuing Guidance.*

In the Repeal NPRM, the Department expressed the concern that both Final Rules delay or prevent the issuance of guidance documents. 86 FR 58046, 58047. In particular, we noted that the Guidance rule established substantial, time-consuming, and resource intensive requirements for the issuance of “significant guidance documents,” such as requirements to submit such documents to OIRA for review prior to publication; provide a public notice-and-comment process; generate an agency response to major concerns raised during the comment period; comply with applicable requirements for significant regulatory actions as set forth in Executive orders; and obtain approval by the Secretary on a non-delegable basis. *See* 45 CFR 1.3(b). Under the Guidance rule, all of these steps are required in combination before a significant guidance can be finalized. The Guidance rule also adds steps to the process of issuing nonsignificant guidance, such as requiring Secretarial approval of guidance that they determine will (1) implicate, including potentially impede, any policy matter of priority to the Secretary, or (2) potentially create a serious inconsistency, or otherwise interfere, with an action taken or planned by another operating division or the Office of the Secretary. 85 FR 78780.

Several commenters confirmed that, in their view, the rules create bureaucratic inefficiencies that slow down or halt the important guidance that stakeholders require to adequately understand and comply with agency rules. These commenters explained that agency guidance documents provide necessary, valuable information to stakeholders. For example, one commenter asserted that healthcare service providers rely heavily on timely guidance, including policy clarification notices, for program operations to ensure timely delivery of care and treatment to their patients. Some commenters asserted that the COVID-19 pandemic has shown the need for HHS to be able to move quickly, especially when public health and human life are

on the line, to keep abreast with the rapid-fire pace of new laws and evolving public health needs, and to respond to the high volume of important stakeholder questions. In contrast, one commenter who supported retention of most of the Guidance rule stated that the Department's concern with potential delays from the new procedures for significant guidance documents was misplaced because there would be relatively few guidance documents that qualify as significant.

We agree with the commenters that explained that the Guidance rule established unnecessary and burdensome inefficiencies, and we disagree with the commenter who suggested that our concerns should be mitigated by the commenter's assertion that relatively few guidance documents would qualify as significant. The definition of "significant guidance" is susceptible to broad interpretation, as noted in the Repeal NPRM. 86 FR 58046. Indeed, although HHS stated in the preamble to the final Guidance rule that it believed there would be relatively few significant guidance documents, 85 FR 78775, we no longer consider that statement to accurately represent past practice. Moreover, the Guidance rule makes it harder for the Department to timely issue guidance to respond to emergencies, rapid changes in the healthcare delivery system, and other critical needs. The additional administrative processes require significant additional time and could serve as a disincentive or obstacle to issuing guidance, particularly for matters requiring expediency. Even the clearance of non-significant guidance takes significant time, because the Department would need to affirmatively decide whether a guidance implicates or potentially impedes any policy matter of priority to the Secretary, or will potentially create a serious inconsistency, or otherwise interfere, with an action taken or planned by another operating division or the Office of the Secretary. These hurdles in turn could make it harder for the Department to expediently respond to stakeholder needs, especially in the cases of public health emergencies or where other critical needs are at issue. Thus, the Department has determined that the delay or non-issuance of guidance could have substantial negative consequences for the public, including for regulated entities.

At least one commenter indicated that these concerns are speculative, overstated, and can be better addressed by fine-tuning the Guidance rule rather than scrapping it entirely. One commenter asserted that our concerns regarding burdens were based on a misreading of the regulations, in that, while the Guidance rule requires that the Secretary must approve certain guidance, the decision on whether a guidance requires Secretarial approval can be delegated. We disagree with the comments and find the delegation point unconvincing because the distinction being drawn by the commenter is not material. Based on our experience, we know that *each* step in the drafting of a document and any associated analysis, review, and clearance process takes time. In the case of significant guidance documents, the Department would have to draft: (1) an initial version of the guidance for public comment; (2) a second version of the guidance taking comments into account; (3) responses to major concerns raised during the comment period; and (4) the analyses required for significant regulatory actions as set forth in Executive orders. Further, we know that adding more steps in the clearance process that include the Department and other Departments throughout the Administration will undoubtedly take even more time. Because this assessment is based on our experience, we disagree with the commenter's assertion that our concern is "speculative." We address the proposals to modify the Guidance rule in greater detail in Section IV.F.2.h., but we note here that we can think of no fine-tuning that would provide adequate time savings, beyond rescinding the rule.

In the case of public health emergencies, some commenters suggested that the exceptions processes for significant guidance documents were sufficient to allow the Department to rapidly respond. Under § 1.3(b)(2)(ii) of the Guidance rule, HHS could elect not to conduct a comment period on significant guidance if it were to find that notice and public comment are impracticable, unnecessary, or contrary to the public interest. Additionally, under § 1.3(b)(4), the Guidance rule permits significant guidance documents to be exempted from applicable requirements "if the Secretary [of HHS] and the Administrator of OIRA agree that exigency, safety, health, or other compelling cause warrants the exemption."

The Department disagrees that the exceptions processes for significant guidance documents provide sufficient flexibility for the Department to respond to public health emergencies quickly and effectively. To rely on the exception under § 1.3(b)(2)(ii), the Department would still need to make findings that public comment would be impracticable, unnecessary, or contrary to the public interest and incorporate the findings and a statement of the reasons into the guidance document. And, to rely on § 1.3(b)(4), the Secretary and OIRA Administrator must come to the described agreement, the Secretary “must make this finding,” and “the significant guidance document must incorporate the finding and a brief statement of reasons in support.” *See* 45 CFR 1.3(b)(4). Even if the exceptions could be met during a public health emergency, these additional processes would still need to be followed and would still consume time and resources in a situation where time is of the essence and limited human resources are better allocated to directly responding to the emergency rather than addressing the procedural requirements of the Guidance rule.

2. *The Guidance Rule’s Notice and Comment Process is not Necessary for Guidance.*

In the Repeal NPRM, the Department expressed the concern that the additional procedures provide little value, because the Department already has all the tools it needs to ensure adequate public notice and participation in the guidance process. The Repeal NPRM indicated that the Department has reconsidered the relative merits of an efficient, flexible guidance process and weighed them against the processes finalized in the Guidance rule, and that the Department favors an approach that is consistent with the APA, which exempts non-binding documents like interpretive rules and general statements of policy from notice-and-comment rulemaking requirements.

Some commenters expressed concerns that the Guidance rule selectively applied portions of the APA to guidance documents, requiring heightened procedural requirements to apply to significant guidance documents in ways not contemplated or authorized by the APA, and that HHS failed to explain the statutory basis authorizing it to apply notice-and-comment

requirements to significant guidance. Another commenter stated that the Guidance rule imposes burdensome requirements akin to rulemaking for significant guidance, despite the Department's history and practice of providing adequate public notice and stakeholder participation in the guidance process.

We agree with these commenters' concerns that the Guidance rule's notice and comment is not necessary for most Department guidance because it is not required by law (except for certain FDA guidance)⁶ and because the Department already has a history and practice of providing adequate public notice and stakeholder participation in the guidance process. Moreover, the Department continues to believe that the relative merits of an efficient, flexible guidance process outweigh the alleged benefits of the processes finalized in the Guidance rule.

Guidance holds an important—and legally distinct—place in the Department's regulatory toolbox: it provides an approach to communicating the Department's policies and interpretations that can be more immediate and clearer than case-by-case adjudication, as well as being faster and more flexible than legislative rulemaking. Through guidance, traditionally, the Department has been able to communicate quickly and responsively its agencies' non-binding current thinking regarding legal interpretations, recommendations, and policies. Timely issuance of guidance is particularly important to parties that are subject to Department regulation because guidance can assist regulated industries by helping guard against unequal treatment, unnecessary costs, and unnecessary risk. Having a robust, efficient guidance system has been especially critical during the COVID-19 emergency. Retaining the Guidance rule, with its relative lack of flexibility and procedural burdens that go far beyond what is required both by law and practice for a transparent and inclusive guidance process, unduly hampers the Department's mission, particularly at this critical time.

3. *The Guidance Rule's Vague Standards are Confusing.*

⁶ See Section IV.A.2. n. 4.

In the Repeal NPRM, the Department expressed concern that the Guidance rule contains vague standards that are likely to cause confusion. For example, the Repeal NPRM noted that the definition of “guidance” in 45 CFR 1.2 is vague and overly broad and could lead to confusion over the type of documents subject to the rule’s requirements. “Guidance” is defined, in part, as a “Department statement of general applicability, intended to have future effect on the behavior of regulated parties and which sets forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation.” *See* 45 CFR 1.2(a). In addition, the preamble to the proposed Guidance rule provided that “guidance may come in a variety of forms, including, but not limited to, letters, memoranda, circulars, bulletins, advisories, and preambles and may include video, audio, and Web-based formats.” 85 FR 51396. The Repeal NPRM stated that this broad definition and understanding could be read to encompass an entire range of documents not intended to serve as guidance, such as resolution documents, agreements, case closure letters, and memoranda published on Department agency websites to inform and educate the general public and regulated entities about agency enforcement activities. 85 FR 78772.

Several commenters agreed with our concern that the definition of “guidance” is too vague. Some commenters remarked that the Department further muddles its definition of guidance documents by stating that material contained within non-guidance could be guidance: “[M]aterial embedded within an advisory opinion or similar letter that otherwise satisfies the definition of ‘guidance document’ would still be guidance for purposes of this rule. If a document addressed to specific individuals nonetheless contains a statement of general applicability setting forth a relevant policy or interpretation that is intended to have future effect by guiding the conduct of other regulated parties, then the document would be a guidance document.” 85 FR 78772.

We agree with these concerns. The broad spectrum of documents encompassed by the definition, as well as the nested feature of guidance-within-non-guidance, could make it difficult

for stakeholders to ascertain which documents are “intended” to be guidance documents. We believe it is reasonable to anticipate that this could lead to confusion over the types of documents subject to the rule’s requirements.

The Repeal NPRM also raised concerns with generalized statements in the Guidance rule on the role and effect of guidance that are not necessary and could cause confusion. For example, § 1.3(a)(1) states, “[u]nder the [APA], the Department may not issue any guidance document that establishes a legal obligation that is not reflected in a duly enacted statute or in a regulation lawfully promulgated under a statute.” The Department continues to see little benefit in this provision if it is intended to capture a current understanding of principles established by the APA. The APA itself governs agency conduct concerning guidance without the need for agency regulations to do so.

4. *Uniform Requirements for the Disclaimer are Confusing.*

The Repeal NPRM expressed concern that the Guidance rule imposed identical requirements on agencies with different legal authorities and mechanisms for achieving their mission. In particular, § 1.3(a)(3)(i) of the Guidance rule requires every guidance document, regardless of the authoring agency or program, to bear the following statement: “The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.” The Repeal NPRM indicated that this universal statement is not appropriate for and cannot cover the range of HHS documents that fall within the definition of “guidance document” under § 1.2(a).

Several commenters expressed concern that the required disclaimer is both confusing and unnecessary. Some commenters remarked that the Department failed to address the confusion created with a guidance document that simultaneously clarifies obligations and declares it has no legal effect. Additionally, some commenters remarked that the Guidance rule fails to explain why a disclaimer is needed, or what problem a disclaimer is attempting to solve; and that

ultimately, courts decide the degree of deference to afford agency action, including guidance.

We agree with these concerns. For example, if a guidance clarifies underlying legal obligations, but then states that the guidance has no force and effect of law, it is reasonable to anticipate that many regulated entities may be confused about how the disclaimer applies to the obligations described in the guidance. Or, if the guidance describes how an HHS agency views certain scientific questions, or how it intends to exercise enforcement discretion, it may be confusing or even nonsensical for the cover to state that the guidance “only” clarifies “existing requirements under the law.”

That said, we acknowledge there may be some circumstances where some form of a disclaimer about the nature of a guidance may be helpful and would not cause confusion. To the extent a disclaimer could be useful for some guidance, the Department does not believe that the solution is to impose a one-size-fits all disclaimer on all guidance. This attempt to fit vastly different documents into one rubric is unnecessary, counterproductive, and likely to confuse the public about the role of different documents. The Department maintains its position described in the Repeal NPRM that a better approach would be for each agency to provide information that is appropriate to the agency’s stakeholders and the expected uses of the document.

Another concern raised in the Repeal NPRM is that the public may be confused by the required statement that incorporation of provisions of a guidance document into a contract would render the guidance binding. One commenter disagreed that this statement would cause confusion because the commenter stated it is common that contracts may incorporate specifically enumerated guidance documents as binding on the contracting party, and it is well understood that compliance with the guidance document becomes mandatory through the party’s affirmative acceptance of the contract. This statement may not be confusing to some stakeholders in some situations, but it may not always be so clear-cut, including for guidance that are unrelated to contracts. In addition, the Department continues to be concerned with the ambiguity of the term “contract,” especially as it relates to assistance agreements, such as grants and cooperative

agreements. While it is understood that assistance agreements have contractual aspects, in several other contexts the Department draws a clear legal and programmatic distinction between contracts and assistance agreements. Nevertheless, both contracts and grants require entering into an agreement that binds both parties to its terms, including in some instances terms found in guidance. Thus, it is reasonable to anticipate that the undefined nature of such a key term in a required disclaimer term could create uncertainty and confusion with some stakeholders, as well as within the Department itself.

5. *The Provisions Governing the Guidance Repository are Problematic.*

The Guidance rule provides for a repository that includes all Department guidance documents, and the rule deems any guidance document not in the repository to be automatically rescinded. 45 CFR 1.4. The Repeal NPRM stated that the Department considers the provisions of the Guidance rule governing the repository to be inappropriate and unnecessary, particularly with respect to the rescission requirement for documents not in the repository. The Department expressed concern that the rescission requirement creates additional burdens among stakeholders by causing confusion about which guidance documents have been rescinded, superseded, or otherwise become obsolete. Under the Guidance rule, rescission can occur simply because a guidance is not uploaded to or is removed from the repository due to human error or technical failures, even if it is publicly available elsewhere. Moreover, the Department questioned whether this rescission approach is consistent with the APA, which requires an agency to consider relevant factors and make policy choices based on those factors.

Several commenters agreed with this assessment, noting the troubling implications of the repository provision. In particular, some commenters expressed concern with 45 CFR 1.4(a)(3)(ii), which rescinds guidance documents previously issued by HHS that are not included in the repository. One commenter noted that since the repository was created, it has been unclear whether omissions in the repository were purposeful or accidental, and that this has been particularly concerning given that the rule intended for the absence of a guidance document from

the repository to in effect rescind that document. The commenter indicated that members of the public—particularly individuals seeking information about Medicaid, Medicare, and other HHS programs—will likely be confused if a guidance document appears on an HHS website, but it is not included in the repository. Commenters further noted that, even if stakeholders petition to reinstate guidance omitted from the repository, such a process would be time consuming, burdensome, and cause uncertainty among the public and regulated entities. Commenters also noted potential confusion regarding joint guidance HHS has issued with other Federal agencies. In particular, they mention a joint guidance regarding the ACA, which appears on HHS and Department of Labor websites, but does not appear in the HHS guidance repository.

We agree with these concerns. Although the Department intends to maintain a centralized location for guidance, which may offer convenience to some users, these comments illustrate how the Guidance rule’s rescission provision is counterproductive and creates confusion. For example, certain users may find it easier to access guidance on an HHS agency or program website rather than in the repository. Once they locate a guidance on the HHS program website, users should not have to take the additional step of searching the repository to determine whether a guidance is in effect. Moreover, if a guidance document is deemed “rescinded” under the Guidance rule because it does not appear in the repository, it is reasonable to anticipate that regulated entities would face a high degree of uncertainty as to the Department’s current thinking, particularly considering the possibility that the guidance may have been unintentionally rescinded because of human error or technical failure. The rescission requirement creates additional burdens among stakeholders by causing confusion about which guidance documents have been rescinded, superseded, or otherwise become obsolete. Additionally, if a guidance document is listed in the repository, but a regulated entity cannot access or view it (for example, as the result of a “broken link” to the guidance document), the regulated entity may act based on a misunderstanding of the Department’s current interpretations and policies. Alternatively, they might choose to engage with the HHS agency about the status of the guidance, which would

consume time and resources for both the requestor and the Department.

These concerns are not speculative. One commenter described difficulties when performing searches of exact guidance names in the “keyword search” function of the repository. Those guidance documents would not always appear in the search results. In addition, filtering guidance documents by topics, HHS division or offices, or language did not always guarantee a guidance document would be retrieved in the search results. The commenter remarked that it has not been uncommon to perform the same search on different days and obtain different search results, many times which did not contain the guidance document an individual is looking for. The commenter stated that the guidance repository appeared to not be working at all on some days, with an error page showing up after a search was performed. Accordingly, this difficulty in finding documents has led to confusion over whether a guidance had been rescinded.

Many commenters supported the existence of a central repository, stating that having a centralized location to search for and identify relevant guidance improves regulated entities’ compliance with agency policies and applicable law. We agree. Consistent with the discussion in the Repeal NPRM, we continue to believe that having a central repository for guidance is a helpful tool, both for stakeholders and the Department, and the Department still plans to maintain a guidance repository. However, the Guidance rule is not needed for the Department to maintain a central repository, and the automatic rescission provision is likewise unnecessary.

The Department continues to believe that the better approach would be to engage with its individual agencies to develop the most efficient and user-friendly repository system that has the flexibility to change with improving technology and experience, and not to be constrained by regulatory requirements. The Department intends for the repository at www.hhs.gov/guidance to remain active, but the additional requirements imposed by the Guidance rule (for example, that removal from the repository would affect rescission of a guidance) would be removed. Guidance will remain validly issued regardless of whether they were ever inadvertently not included in the repository.

In the Repeal NPRM, the Department invited stakeholders to comment on their experience with the repository and to comment on how the Department can improve its usability and utility. In response to this request, the Department received several helpful comments on how to improve the usability of the repository. We appreciate the comments, and we will continue to consider them as we work to ensure the repository is as complete, user-friendly, and current as possible.

6. *The Guidance Petition Process is Unnecessary and Burdensome.*

Section 1.5 of the Guidance rule established a petition process under which an interested party may petition the Department to withdraw or modify any particular guidance document. The provision requires the Department to issue a substantive response within 90 days regardless of the petition's subject matter or merits or competing public health priorities. The Department has decided to repeal this new guidance petition process because it is unnecessary, burdensome, and not legally required.

One commenter noted that it had commented earlier on the proposed Guidance rule that it was unclear how this provision impacted the status of guidance or any right to challenge guidance under the APA, and the final Guidance rule did not address its concerns. However, because the Department has decided to repeal the regulation establishing the new petition process, it is unnecessary for us to clarify what the effects of this provision would have been on the status of guidance or any right to challenge guidance under the APA.

Another comment opined that eliminating the petition process entirely would effectively leave interested parties with no formal methods other than litigation to seek the withdrawal or modification of improper or unwise guidance. We disagree. As discussed in the Repeal NPRM, the new guidance petition process created by the Guidance rule is unnecessarily duplicative of other already existing methods through which stakeholders can challenge agency decisions relating to guidance applicability or request changes in or the rescission of existing guidance. These methods include (but are not limited to): FDA's citizen petitions process related to "any . .

. form of administrative action,” 21 CFR 10.25(a); FDA’s GGP regulation providing that affected parties may suggest at any time that FDA withdraw an already existing guidance document and may elevate concerns that an FDA employee has not followed the procedures in the GGP regulation or has treated a guidance document as binding, 21 CFR 10.115(f)(4) & (o); the appeals process for facilities that disagree with decisions involving application of guidance governing Medicare eligibility and participation, 42 CFR part 498; and already-existing relationships between regulated entities and HHS agencies that allow stakeholders to express comments, suggestions, or concerns with guidance in their formal and informal discussions with agency employees. Furthermore, we note that, while stakeholders have a right to petition government agencies under the First Amendment, the Petition Clause does not require “government policymakers to listen or respond to individuals’ communications on public issues.” *Minn. State Bd. for Cmty. Colleges v. Knight*, 465 U.S. 271, 285 (1984); *see also We the People Found., Inc. v. United States*, 485 F.3d 140, 143 (D.C. Cir. 2007); *Small Bus. in Transp. Coal. v. U.S. Dep’t of Transp.*, 2021 WL 4399581, at *14 (D.D.C. Sept. 27, 2021).

The same commenter further stated that, in the Repeal NPRM, the Department’s “real concern” with the new guidance petition process was that the current deadline is too short, rather than its stated concern that process itself is unworkable in practice. The comment further asserted that HHS had offered insufficient evidence that this 90-day deadline for responding to petitions had proven unworkable in practice.

We agree with the comment to the extent that it acknowledges our concern with the 90-day deadline, but that represents only part of the problem. In practice, since the inception of the good guidance petition process, most submissions that have come to the Department through this process have not been petitions “to withdraw or modify any particular guidance document.” 45 CFR 1.5. The Department has expended substantial resources to respond to submissions asserted to be petitions under § 1.5 that: ask about where to find information in the guidance repository; complain about vaccination policies; query for information for how to file personal medical

claims; and request the agency to take action to withdraw policies with which the petitioners disagree. Even though these submissions do not qualify as good guidance petitions under the Guidance rule, they require significant time and effort to determine whether the submission meets the Guidance rule's requirements and draft a substantive response. For petitions that do qualify under the Guidance rule, even more effort is necessary to review the scope and nature of the request, draft and revise responses to the petitions, and complete any necessary clearance.

For example, one petition ostensibly submitted under § 1.5, requested that HHS, CDC, FDA, and “all other component agencies of HHS” revise each guidance document, order, and regulation that related to mask-wearing or vaccine administration for children in the context of COVID-19. As noted above, although the Department ultimately concluded that petitioner had not properly invoked § 1.5, deliberating over and responding to the petition consumed a substantial amount of time from attorneys and subject matter experts in the Office of the Secretary, CDC, and FDA, and, because of the deadline, those deliberations were prioritized over other matters that had more potential to advance public health.

It is not necessary or appropriate to establish a special guidance petition pathway. In operation, it has led HHS agencies to sort through submissions that were not submitted properly under the Guidance rule. Moreover, we no longer see any utility in retaining a process that forces the agency to expend its valuable resources when stakeholders already have other methods to bring guidance-related concerns to the agency. As explained in the Repeal NPRM and borne out in actuality, the guidance petition process is structured in a way that leads to wasting Government resources on potentially meritless petitions. For example, the process allows a petitioner to petition for hundreds of guidance documents to be rescinded at once, and/or allows one or many petitioners to re-petition regarding a single guidance document multiple times.

Finally, one comment expressed concern that rescinding the Final Rule would result in only some agency components with petition processes in place, and that this would be less effective than keeping one petition process for the whole Department. As we discuss in Section

IV.A.4.b. above, a single set of procedures for guidance documents and civil enforcement for the entire Department is incompatible with the efficient and effective administration of a Department as large and diverse as HHS. We therefore disagree that it is overall less effective to have different petition processes depending on the agency component.

7. *Comments Raising Issues Specific to CMS do not Support Retention of the Guidance Rule.*

One commenter, who did not believe HHS should pursue a wholesale repeal of the Guidance rule, instead recommended that the agency take steps to systematically re-evaluate its guidance practices. In particular, the commenter believed CMS should consider the timing of rulemaking and guidance for the Medicare Part D prescription drug program and recommended that regulations be issued earlier to allow time for development of guidance and for stakeholders to prepare for and implement new regulatory requirements before the start of the applicable plan year. This commenter also believed HHS should address the limits of guidance and when it is inappropriate to use. As an example, the commenter noted that the requirements included in contracts with Part D plan sponsors should be subject to full notice-and-comment rulemaking.

We appreciate these suggestions and will take these recommendations into consideration when planning future rulemaking, including for the Part D program. However, for the reasons discussed in the Repeal NPRM, we continue to believe it is necessary to repeal the Guidance rule to enable efficient and effective administration of all HHS programs.

Another commenter opined that the Medicare program would significantly benefit from the Guidance rule and urged HHS to retain it. Unregulated guidance documents, this commenter stated, have a significant impact on healthcare organizations, particularly in the case of accrediting organizations (AOs), due to the unique nature of the deeming partnership with CMS. The commenter further stated that certain Department communications can go beyond the informational purposes mentioned in the proposed rule and may contain meaningful policy changes that can be unnecessarily disruptive and costly, and therefore should undergo public review. For example, the commenter stated that CMS often issues guidance to states and agency

regional offices that impact healthcare organizations and accredited bodies. These documents may contain new requirements that can impact AOs and accredited organizations, despite not having undergone a notice-and-comment period. The commenter further stated that healthcare organizations and the public are often unaware of certain policy memoranda and frequently do not know where to find them for review. For example, the commenter said certain memoranda are kept in a portal for state and regional offices and thus stakeholders may not know when new ones are published.

We disagree with the characterization that, without the Guidance rule, Department guidance in general, and CMS guidance in particular, is unregulated. We note that, although we are repealing the Guidance rule, we are still bound by the APA and—when administering the Medicare program—the *Allina* holding (interpreting section 1871 of the Social Security Act), both of which require rulemaking whenever we “establish[] or change[] a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [Title XVIII of the Social Security Act].” In the particular context of Medicare, we expect the same level rulemaking activity after the repeal as previously, including while the Guidance rule has been in effect. The APA requires all enforceable standards to go through notice-and-comment rulemaking; to the extent that CMS continues to issue sub-regulatory guidance, they are intended to provide additional information, not establish or change substantive legal standards. Finally, we note that section 1865 of the Social Security Act only requires accrediting organizations to demonstrate to CMS that their accreditation programs indicate that our “applicable conditions or requirements . . . are met or exceeded.” The statute does not require accrediting organizations to adopt any CMS guidance or other sub-regulatory policies or methodologies.

In contrast, other CMS stakeholders supported repeal of the Final Rules. For example, one commenter supported repeal of the Guidance rule because it promotes confusion among beneficiaries, state agencies, and other Medicaid and Children’s Health Insurance Program

(CHIP) stakeholders. The commenter further stated that the Guidance rule created a central guidance repository that duplicates and undermines the guidance compilation maintained by the Center for Medicaid and CHIP Services. We thank the commenter for its input and agree that the Guidance rule should be repealed.

8. *The Guidance Rule Conflicts with Preexisting FDA Regulations.*

The Guidance rule has presented unique implementation problems for FDA. As explained in the preamble to the Repeal NPRM and above, FDA, unlike the other divisions of HHS, has long operated under a statutory provision concerning guidance and has its own GGP regulations, which address FDA's practices related to guidance documents, including practices and procedures for issuing, revising, and implementing guidance documents. *See* 21 U.S.C. 371(h); 21 CFR 10.115. FDA also operates under longstanding regulations regarding citizen petitions, *see* 21 CFR 10.30, 10.31, which interested persons have used to request that FDA take certain actions with regard to FDA guidance documents.

The Repeal NPRM discussed several problems with applying the Guidance rule to FDA. First, it noted that the Guidance rule establishes standards and processes that overlap with but are distinct from FDA's existing requirements, which creates practical difficulties and confusion. For example, 21 U.S.C. 371(h) and 45 CFR 1.3(b)(4) contain different standards for dispensing with prior public participation for certain guidance documents. Second, the application of the Guidance rule to FDA guidance presents complex unaddressed challenges. For example, if a guidance document is erroneously rescinded under § 1.4(a)(2) of the Guidance rule, FDA would need to consider how to repromulgate its guidance in a manner consistent not only with the Guidance rule, but also with its own statute and regulations. Third, it is inefficient and confusing for regulated entities as well as FDA staff to toggle back-and-forth between HHS and FDA Guidance rules to try to figure out what the requirements are and, in some instances, to meet the requirements of the HHS Guidance rule, the FD&C Act, and FDA's GGP regulation.

One commenter discussed whether the Guidance rule should apply to FDA, particularly considering the agency's preexisting regulations. Although the commenter did not support repeal of the Final Rules overall, it did recommend that FDA be exempted from the Guidance rule because "the superimposition of the HHS rule has led to some confusion." HHS agrees that this superimposition has led to problems, including confusion, and that the rule should not apply to FDA. Prior to the Guidance rule, stakeholders were familiar with FDA practices and processes, which had been in effect for twenty years. The Guidance rule has called those processes into question and introduced new, burdensome procedures that will make it more difficult for regulated entities to receive important non-binding information. HHS continues to believe that repealing the Guidance rule is important to stabilize and clarify the regulatory regime for FDA guidance documents.

E. Comments on Specific Issues Related to the Civil Enforcement Rule

1. *The Civil Enforcement Rule Established an Unnecessary and Confusing Overlay of New Procedural Requirements.*

In the Repeal NPRM, the Department explained that the requirements in §§ 1.6 through 1.9 create conflicts with existing agency processes and regulations. The various agencies under the HHS umbrella each have procedural regulations, some of which have been specifically designed to govern a particular type of proceeding. *See, e.g.*, 21 CFR part 17 (procedures governing hearings concerning the imposition of civil money penalties by FDA); 42 CFR part 488 (CMS and State Agency survey, certification, and enforcement procedures for Medicare providers and suppliers); 42 CFR part 498 (appeals procedures for determinations that affect participation in the Medicare Program); 45 CFR part 160, subpart E (procedures governing hearings challenging the imposition of civil monetary penalties in Health Insurance Portability and Accountability Act (HIPAA) cases). The procedures required under the Civil Enforcement rule do not adequately account for these pre-existing, agency-specific procedures, nor do they account for the differences between agencies within the Department. Instead, the Civil Enforcement rule dictates an overlay of new, and in some cases redundant, requirements.

Commenters confirmed these concerns. For example, one comment explained that the Civil Enforcement rule undermines the well-developed procedures and plans that are tailored by each agency to govern specific types of proceedings.

The Department agrees with this comment. HHS agencies have designed their procedural regulations to comply with principles of due notice, fairness, and transparency. Parties that are subject to civil administrative enforcement actions and adjudications under the existing procedures established prior to the Civil Enforcement rule are routinely provided with sufficient notice of the action, adequately informed of laws and regulations to which they are subject to, fully instructed on contesting or appealing agency determinations prior to actions of legal consequence, and protected from unfair surprise. To the extent the requirements of the Civil Enforcement rule diverge from the existing procedures, the conflict creates confusion for both HHS agencies and regulated parties and could delay or prevent civil enforcement.

2. *Hurdles will Leave Bad Actors in the Market for Longer.*

In the Repeal NPRM, the Department explained that the processes and procedures set forth in the Civil Enforcement rule create unnecessary hurdles and roadblocks for agency actions, to the detriment of the public health and other national priorities. 86 FR 58050. Comments confirmed that the Civil Enforcement rule creates unnecessary hurdles for the Department. One comment further explained that the lengthy procedures established by the rule hamper enforcement which results in leaving bad actors (such as those committing billing fraud) in the market for a lengthier period of time. The comment further noted that, although the Civil Enforcement rule contains an exception for “health, safety, or a similar emergency,” this exception was inadequate to address the concern that the rule institutes rigid requirements that could create roadblocks to agency enforcement actions.

The Department agrees with these comments. For example, § 1.9 requires the Department to follow certain steps before taking civil enforcement actions, including providing parties with an initial notice of the agency’s legal and factual determinations, an opportunity to

object or respond, and the Department’s “written response” to the affected party’s objections. In issuing the Civil Enforcement rule, the Department stated that it anticipated that existing HHS procedures already satisfied the requirements established in § 1.9. 86 FR 3012. Upon reconsideration, the Department now finds that the Civil Enforcement rule creates a rigid, burdensome, and resource-intensive path for Department staff, which is unnecessary when other tools in use, such as informal negotiation, could be more efficient and effective. *See, e.g.*, FDA’s Regulatory Procedures Manual section 10-3 (describing FDA’s use of “regulatory meetings” as an option in seeking industry compliance) (available at <https://www.fda.gov/media/71765/download>).

Section 1.7(a) prohibits the Department from applying “standards or practices” in a civil enforcement action that have not been “publicly stated.” That new restriction on the Department’s authority is not required under settled case law,⁷ and it could interfere with the Department’s ability to enforce new laws and address emerging threats, particularly through the use of adjudicatory proceedings.

We also agree with the commenters that the exception in § 1.9 involving “a serious threat to health, safety, or similar emergency,” 86 FR 3013, does not adequately address the concerns with that regulation. For example, the exception does not address fraudulent actors who drain the Department’s resources when allowed to remain in Departmental programs. It is not in the public interest for an HHS agency such as CMS to take fewer enforcement actions against providers and suppliers who fraudulently bill patients and harm the Medicare trust funds. Delayed action against fraudulent billing would allow further diversion of taxpayer dollars and loss of program funding, forcing divisions to reprioritize program resources. Additionally, the

⁷ *See SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947) (“[P]roblems may arise in a case which the administrative agency could not reasonably foresee Hence, we refuse to say that the Commission, which had not previously been confronted with the problem of management trading during reorganization, was forbidden from utilizing this [adjudicatory] proceeding for announcing and applying a new standard of conduct”); *Martin v. Occupational Safety & Health Rev. Comm’n*, 499 U.S. 144, 154 (1991) (“Within traditional agencies . . . adjudication operates as an appropriate mechanism not only for factfinding, but also for the exercise of delegated lawmaking powers, including lawmaking by interpretation.”).

exception does not alleviate the burden on the Department, because the process, including the Department's written response to the party's objections, must still be followed "as soon as practicable." 86 FR 3013. Finally, analyzing whether a particular action falls into the exceptions set forth in § 1.9(c) would itself require an expenditure of time and resources that could delay actions needed to be taken on a time-sensitive basis.

3. *"Fairness and Notice" Provisions Exceed Existing Legal Requirements and are Burdensome.*

The Civil Enforcement rule imposed a series of limitations on enforcement actions by requiring prior notice of various positions in a variety of contexts. For example, the rule imposes a requirement that, if the agency intends to rely on a decision to assert new or expanded claims of jurisdiction, it must have published the initial decision in the Federal Register or the HHS guidance repository before the conduct subject to enforcement occurs. 45 CFR 1.8. Similarly, the Civil Enforcement rule prohibits an agency in taking civil enforcement action from applying standards and practices that have not been publicly stated or citing guidance that does not appear in the HHS guidance repository. 45 CFR 1.6 & 1.7. Although the preamble to the Civil Enforcement rule and some commenters attached a "fairness and notice" label to provisions, that preamble conceded that the requirements in the regulations "exceed the requirements imposed by the Due Process clause" and "may impose a burden by delaying the time until HHS can take actions with legal consequence." *See* 86 FR 3013.

Several commenters supported the "fairness and notice" requirements and thus opposed their repeal. The comments noted that, in the Civil Enforcement rule preamble, HHS had explained that these regulations would give regulated parties a method to challenge certain types of unfair enforcement. The commenters maintain that the Repeal NPRM provided an inadequate explanation as to why the Department had changed its mind. One comment suggested that the "fairness and notice" requirements could be revised to narrow their scope and reduce their burden.

We disagree with the positions advocated by these commenters. As the Civil Enforcement rule acknowledged and we agree, these “fairness and notice” provisions exceed the requirements of existing law. We also find that neither the Civil Enforcement rule nor the commenters provided a persuasive explanation as to why these additional regulatory hurdles are necessary to advance the interests of justice. As we explained in the Repeal NPRM and above, the Department continues to abide by its longstanding commitment to follow applicable principles of due process and administrative law, and these well-established requirements guarantee that fair notice is provided to the subjects of civil enforcement actions. Accordingly, we conclude that these additional regulatory hurdles are unnecessary to ensure fairness.

The preamble to the Civil Enforcement rule also acknowledged that these “fairness and notice” procedures would burden and delay HHS enforcement actions. *See* 86 FR 3013. Again, we agree with that assessment. The preamble to the Repeal NPRM also raised the additional concern that ambiguities in the new procedural requirement could lead to spurious challenges to valid enforcement actions and adjudications, which would significantly impede the Department’s ability to take enforcement actions and would divert resources from mission-critical activities. Although the Civil Enforcement rule concluded that these provisions would benefit regulated industry, or at least those who are the subject of enforcement actions, there was no explanation of how these provisions protect or advance public health and welfare. Indeed, by impeding legitimate enforcement actions against bad actors, the Department now concludes that these provisions adversely impact the public health and welfare.

As described in this preamble, the Department has changed its position on the value of the entirety of the Final Rules, in that they impose a rigid layer of bureaucracy that impedes the effective operations of the Department and will deflect resources from mission critical endeavors. The “fairness and notice” requirements are no exception. They would require extra steps as prerequisites to enforcement action, which slow the initiation of such actions, create new grounds for challenging Department actions, and absorb resources that would otherwise be dedicated to

other Department objectives. As such, they are contrary to the policies and goals of the Biden-Harris Administration to ensure that HHS can appropriately leverage administrative tools to protect and advance the public health and welfare and to efficiently and effectively administer its wide array of programs.

F. Comments on Legal Issues

1. *Take Care Clause and Separation of Powers Doctrine*

Several commenters noted that the Final Rules create procedural requirements beyond those in existing law. One commenter disagreed with that view, stating that the rules strike no new legal ground and only capture existing law under the Fifth Amendment, the Appointments Clause, the separation-of-powers doctrine, the APA, and the Freedom of Information Act (FOIA). The commenter stated that repeal of the rules would amount to HHS actively ignoring or overruling relevant law and would constitute a violation of the Take Care Clause, U.S. Const. art. II, sec. 3, and the separation-of-powers doctrine. The commenter further stated that EO 13992 was unlawful and could not provide an adequate basis for the repeal because the President cannot make a policy choice to derogate portions of the Nation's laws.

HHS agrees with the commenters who stated that the Final Rules go beyond existing legal requirements and disagrees with the arguments that the repeal is unlawful. For example, for significant guidance, as defined in 45 CFR 1.2(a), the Department is required to submit such documents to OIRA for review prior to publication, provide public notice-and-comment process, generate an agency response to major concerns raised during the comment period, comply with applicable requirements for significant regulatory actions as set forth in Executive orders, and obtain approval by the Secretary on a non-delegable basis. 45 CFR 1.3(b). The rules also create a special process for the submissions and review of petitions related to guidance, which includes a 90-day deadline for the Department's response. 45 CFR 1.5. The Department is not aware of any prior existing law that mandates these procedures. Indeed, when HHS promulgated the Final Rules, it acknowledged that the rules went beyond existing law. *See, e.g.*, 85 FR 78777 (relying

on agencies' authority to "grant additional procedural rights in the exercise of their discretion" as a basis for the rule); 86 FR 3013 ("[§ 1.9] may exceed the requirements imposed by the Due Process clause of the Constitution").

Because the Final Rules go beyond existing legal requirements and constitute an exercise of HHS discretion, HHS has discretion to eliminate these self-imposed procedural requirements. The President's EOs referenced in this comment, including EO 13992, did not direct agencies to derogate portions of the nation's laws; rather, they provided policy direction in the application of the Department's discretion.

Furthermore, even assuming that some portions of the regulations only codify existing legal principles, HHS does not agree that it is required as a matter of law to retain these portions of the regulations. The commenter cited the Take Care Clause and the separation-of-powers doctrine, which require the President and executive officials to adhere to existing law. *See, e.g., Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579 (1952). But the Department can adhere to the law, and fully intends to do so, without maintaining regulations that attempt to codify that law. The requirements of existing law from applicable statutes, case law, and the Constitution already bind HHS, and there is no legal requirement that HHS duplicate them in regulation. Nor does HHS agree that such a requirement takes hold only once the regulations have already been promulgated. We are not aware of any legal principle that requires agencies to maintain regulations seeking to codify existing law after they have been issued.

The Department's choice to repeal the Final Rules in no way reflects disagreement with or a rejection of its legal duties. On the contrary, given the evolving nature of the law and the complexity of current precedent, as discussed in Section IV.F.2.c. below, HHS believes it will be *better* positioned to comply with the law and to "take Care that the Laws be faithfully executed" by repealing these regulations. U.S. Const. art. II, sec. 3.

2. *Administrative Procedure Act*

a. Adequate justification for repeal

Several commenters asserted that, as a general matter, HHS had not adequately justified the repeal under the APA and the Supreme Court's precedents in *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983) and *Dep't of Homeland Sec. (DHS) v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891 (2020).

HHS disagrees with the commenter's assertion that the repeal does not comply with the APA. In *State Farm* and *Regents*, the Supreme Court considered the rescission of two different substantive policies and laid out certain standards for agencies to meet in justifying their rescission decisions. *E.g.*, 463 U.S. at 42 (requiring "reasoned analysis" and "consideration of relevant factors"). However, as an initial matter, it is not clear that these standards apply equally to rules governing agency procedures. The Supreme Court has recognized a "very basic tenet of administrative law that agencies should be free to fashion their own rules of procedure." *Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council*, 435 U.S. 519, 544 (1978); *see also Ass'n of Bus. Advoc. Tariff Eq. v. Hanzlik*, 779 F.2d 697, 701 (D.C. Cir. 1985) ("It is too well-established to be seriously questioned that agencies are empowered to order their own proceedings and control their own dockets."). This principle is an "outgrowth of the congressional determination that administrative agencies and administrators will be familiar with the industries which they regulate and will be in a better position than federal courts or Congress itself to design procedural rules adapted to the peculiarities of the industry and the tasks of the agency involved." *Id.* at 525 (quoting *FCC v. Schreiber*, 381 U.S. 279 (1965)). When rules are procedural in nature, it makes sense for courts to give agencies greater leeway to organize their operations and deploy resources as they see fit. HHS and its agencies are uniquely suited to understand which procedures will best facilitate the execution of its duties. The Final Rules constitute self-imposed procedural requirements governing agency, not private, conduct. Now that HHS has determined that these procedures will not best enable the Department to serve its mission, these discretionary revisions of its procedural rules are not subject to the APA standards for changing substantive policy under *State Farm* and *Regents*.

Indeed, it is not clear that there can be *any* judicial review of these discretionary procedural rules, let alone under the standards applied to the review of substantive rules. The statutory authority cited as the bases for the Final Rules provides in relevant part that “[t]he head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.” 5 U.S.C. 301. As the Supreme Court has explained, the APA at 5 U.S.C. 701(a)(2) “makes it clear that ‘review is not to be had’ in those rare circumstances where the relevant statute ‘is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion.’” *Lincoln v. Vigil*, 508 U.S. 182, 191 (1993) (quoting *Heckler v. Chaney*, 470 U.S. 821, 830 (1985)). Because 5 U.S.C. 301 contains no judicially manageable standard, the repeal of the Final Rules should not be subject to judicial review.

Even assuming the APA standards for changing substantive policies apply, HHS’s decision is adequately justified under *State Farm* and its progeny. As discussed in more detail elsewhere in this preamble, HHS’s reasons for repealing the Final Rules include that the Final Rules: (1) run counter to the Administration’s goals of advancing public health and welfare; (2) impose burdensome standards and procedures; (3) harm marginalized constituencies; (4) impede Department flexibility; and (5) divert limited Department resources. The Supreme Court has explained that, when changing course, an agency “need not demonstrate to a court’s satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates.” *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515-16 (2009). HHS’s new policies, as articulated in this preamble and in the Repeal NPRM, are permissible under the statute and are supported by good reasons; therefore, this repeal action complies with the APA.

HHS recognizes that, in some cases, an agency is required to provide a more detailed justification for rescinding a policy than what would suffice for a new policy. This may be true “when, for example, [the] new policy rests upon factual findings that contradict those which underlay its prior policy.” *Id.* at 515. HHS believes its justification for this repeal is far more detailed and comprehensive than what was provided for the Final Rules’ promulgation. For example, HHS has described its current experience with the rule (*see* Section IV.F.2.e.) and has explained in detail the specific reasons why this repeal is appropriate.

Regardless, because the Final Rules were grounded mainly in policy and political justifications rather than factual findings, the Department does not believe the “more detailed justification” standard applies. For example, the preambles to the Final Rules cited: the previous Administration’s regulatory reform initiative; generalized policy views that the additional procedures were favorable because they would increase accountability, transparency, and fairness; and two Executive orders that have since been revoked. For the most part, the preambles to the proposed Guidance rule and both Final Rules did not identify specific factual concerns that the Department sought to address through the rulemakings.⁸ Indeed, one commenter in this rulemaking criticized the Guidance rule for “fail[ing] to provide any evidence-based discussion to support its contention that the [Guidance r]ule would benefit ‘the public, and, in particular, regulated parties.’” Overall, both rules were justified mainly on policy grounds, which, in HHS’s current view, overlooked serious drawbacks of the requirements. Given those high-level and cursory justifications, we believe that the justifications provided in this repeal rulemaking are more than adequate.

As noted above, *State Farm* requires agencies to consider “relevant factors.” Some commenters identified factors that they believed HHS should have considered in its decision-

⁸ One exception is a statement in the preamble to the Guidance rule that regulated entities have difficulty locating and identifying operative guidance documents, which HHS intended to address through the guidance repository. 85 FR 78781. However, as discussed in Section IV.D.5 above, HHS plans to maintain the guidance repository and to work towards improving its functionality, but without the automatic rescission provision and without a governing regulation.

making, such as asserted benefits of these rules. Although HHS is not convinced the *State Farm* standard applies, those factors are addressed individually in Section IV.F.2.e and f below.

b. Clear error of judgment

One commenter asserted that *State Farm* requires HHS to demonstrate how the adoption of the guidance and civil enforcement rules was “a clear error of judgment” in order to justify the repeal.

HHS does not agree that *State Farm* requires an agency to show that the prior policy choice was “clear error,” even assuming the *State Farm* standard applies here. In *State Farm*, the Supreme Court stated that in reviewing an agency’s explanation for a repeal, it “must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.” 463 U.S. at 43 (internal quotations omitted). This language requires courts to evaluate whether the repeal decision was “clear error”; it does not require an agency to show that the prior policy was clear error. *E.g., State Farm Mut. Auto. Ins. Co. v. Dole*, 802 F.2d 474, 486 (D.C. Cir. 1986) (“clear error” standard applies for a court to “overturn agency action”). As noted elsewhere in this preamble, to justify a repeal, an agency needs to adequately explain why the new policy is permissible under the statute and that there are good reasons for its new position. *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515-16 (2009). An agency “need not demonstrate to a court’s satisfaction that the reasons for the new policy are better than the reasons for the old one.” *Id.* HHS has met that standard, as discussed in the previous comment response.

Nevertheless, the Department now believes the Final Rules represent a misjudgment. The Final Rules were based on policies announced in Executive orders that this President revoked because those policies were counter to the objectives of the Biden-Harris Administration. As explained, these current objectives include using available tools of Federal administrative agencies to, among other things: confront the urgent challenges facing the Nation; equip executive departments with flexibility to use robust regulatory action to address national

priorities; pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality; and protect and strengthen the ACA and make high-quality healthcare accessible and affordable for every American. Because the Final Rules place obstacles to achieving these objectives, their issuance was contrary to the best interests of the public health and welfare, and therefore represents a clear error in judgment. Moreover, these procedural regulations were issued at the tail end of one Administration to govern the procedures to be followed by the next Administration, which in itself is a regrettable misjudgment.

c. Reflection of existing law

Some commenters asserted that portions of the Final Rules track existing judicial precedent and questioned HHS's rationale under the APA for repealing the rules where they reflect existing law. For example, one commenter stated that HHS should maintain the definition of guidance because it matches existing law. Another commenter objected to HHS's grounds for repealing § 1.7 because, in the commenter's view, § 1.7 codifies existing law under *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142 (2012). One commenter stated that HHS lacked a "satisfactory explanation" for the rescinding the Final Rules because the rules are based on binding Federal-court precedent.

This argument is similar to the argument discussed in Section IV.F.1. above in the context of the Take Care Clause and separation-of-powers doctrine, only here the comments are relying on the APA. As explained in that comment response, HHS does not agree that the Final Rules only capture existing legal precedent. The Final Rules go beyond existing law, such as by imposing new procedures on the issuance of guidance.

For example, with respect to § 1.7, HHS continues to believe that provision is not required under settled case law. In *Christopher v. SmithKline Beecham Corp.*, the Supreme Court declined to give controlling deference to an agency interpretation of an ambiguous regulation that was advanced in an amicus brief, based in part on concerns about unfair surprise.

Instead, the Court analyzed the interpretation under the “*Skidmore* deference” framework and accorded the agency’s interpretation “a measure of deference proportional to the ‘thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade.’” 567 U.S. at 159 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001)). Under this framework, the Court determined that the agency’s interpretation was unpersuasive. The Court did not invalidate the interpretation on procedural grounds or state, as a matter of law, that agencies cannot announce and apply new legal standards in enforcement proceedings. Yet that is what § 1.7 provides: it bars HHS from applying standards or practices in civil enforcement proceedings that have not been “publicly stated.” That position is inconsistent with *SEC v. Chenery Corp.*, in which the Supreme Court held that agencies can use adjudicatory proceedings to announce and apply new standards of conduct. 332 U.S. 194, 203 (1947). Although the commenter suggests that *Christopher* overruled *Chenery*, the *Christopher* decision does not take on the same question or even mention *Chenery*.⁹

Insofar as there are portions of the regulations that only codify existing legal principles, this rulemaking is not intended to reflect objection to or disagreement with these principles. HHS is fully committed to complying with applicable law. Nevertheless, HHS is opting not to retain regulations seeking to codify existing precedent for several reasons. First, many of the legal principles at issue here are nuanced. HHS recognizes that there is risk in attempting to reduce these principles to regulatory language and believes that it will be difficult for the Department to ensure that its regulations fully capture the context and meaning of relevant court decisions, even with great thought and care. Second, amending rules codified in the CFR is generally time-consuming and resource-intensive. Thus, as legal precedent evolves, the

⁹ The commenter cites *ExxonMobil Pipeline Co. v. U.S. Department of Transportation*, 867 F.3d 564 (5th Cir. 2017), for the proposition that *Christopher* establishes that regulatory agencies cannot announce and apply new legal standards in enforcement proceedings. However, like *Christopher*, *ExxonMobil Pipeline* addressed unfair surprise in the context of applying deference to an agency’s interpretation. See 867 F.3d at 573. Moreover, also like *Christopher*, *ExxonMobil Pipeline* does not mention *Chenery* and does not suggest that that *Christopher* overruled that case.

regulations could become outdated and could create administrative challenges, confusion, and potential conflicts for the Department. Third, as noted in the Repeal NPRM, we see little benefit in these provisions because the APA already governs agency conduct without the need for agency regulations. 86 FR 58049. In light of these considerations, we have decided that the practical and procedural risks outweigh any benefits of attempting to codify existing legal principles, and so we have determined not to retain such regulations.

d. Reliance on Executive orders

One commenter stated that the current Administration's Executive orders, including EO 13992, do not provide adequate justification for rescinding regulations, citing *California v. Bernhardt*, 472 F. Supp. 3d 573, 605 (N.D. Cal. 2020). In that case, the court explained that Executive orders cannot eliminate statutory mandates. *Id.*

We do not find the comment persuasive for several reasons. First, EO 13992 does not eliminate any statutory mandates; rather, it revokes Executive orders issued by the previous Administration and provides policy direction in the application of the Department's discretion, as noted in Section IV.F.1 above. Second, given that HHS has discretion in this area, it is entirely appropriate for the Department to cite to the policy direction set forth in the current Administration's Executive orders as part of its rationale for repealing the Final Rules. Indeed, we note that the Final Rules themselves were based on policy direction in Executive orders issued by the previous Administration. Third, as explained in this preamble and in the Repeal NPRM, HHS has reasons beyond the inconsistency with the Executive orders for repealing the Final Rules. Other reasons include that the Department no longer believes that the Final Rules will best equip it to serve its mission, no longer agrees with codifying these types of Department-wide procedures in regulation, and no longer supports a one-size-fits-all approach to guidance and civil enforcement procedures for HHS. These reasons are sufficient under relevant case law. This is particularly true where the Final Rules govern only agency processes and were based almost entirely on policy justifications, including (now-revoked) Executive orders.

e. Specific examples

One commenter objected to HHS's harm-based rationale for repealing the Final Rules because the Repeal NPRM lacked sufficient specific examples. The commenter asserted that HHS had only "speculate[d]" that harms could ensue and offered "purely hypothetical concerns." The commenter indicated that a "satisfactory explanation" under *State Farm* requires HHS to produce specific examples of harm caused by the Final Rules over the past nine months, such as examples of how the guidance processes have caused delay or details about the resources expended on guidance petitions.

HHS's concerns about the harms of these rules are not speculative or hypothetical. In the relatively short time that the Final Rules have been in effect, they have required HHS agencies to prioritize and divert resources to, for example: clearing a Medicaid guidance under the more cumbersome new processes, which took weeks longer than anticipated and delayed the timely communication of needed information to program beneficiaries; responding to petitions submitted under 45 CFR 1.5 that were ultimately found not to even satisfy the requirements for a guidance petition but nevertheless demanded significant time and effort; quickly uploading guidance documents into the guidance repository to avoid automatic rescission; preparing the analysis of the economic impact of certain significant guidance documents, which is especially challenging given the non-binding nature of guidance; responding to questions from stakeholders who are confused by the new guidance disclaimer language; and modifying certain civil administrative procedures even though they generally would have included notice and opportunities for engagement, because those procedures did not include the scripted process in the Civil Enforcement rule. These and other experiences have informed HHS's decision-making for this repeal.

The Department also notes that the procedures for significant guidance are modeled on procedures for issuing legislative rules, and HHS and the public are aware of the difference in time required to issue a guidance (at least prior to the Guidance rule) as compared with a

legislative rule. Considering this well-established differential, we are puzzled that anyone would dispute that these significant guidance procedures will cause delay in the issuance of significant guidance.

Beyond these harms, the Repeal NPRM cited various other examples of harm, including CMS's difficulties with the guidance repository, the inconsistency between the HHS and FDA guidance requirements, and the confusion created by a new overlay of civil administrative enforcement procedures on existing procedures. 86 FR 58048, 58050, 58051. HHS also previously discussed how the Guidance rule causes confusion when it described commenters' concerns about the definition of guidance, the definition of significant guidance, and the disclaimer requirement. 85 FR 78772, 78774, 78778. Comments in this rulemaking have reiterated that confusion and the uncertainties created by the rules, among other problems.

HHS's decision to repeal these rules is also based on a risk of significant future harm. That risk exists because the rules are susceptible to broad interpretation and multiple meanings. The Repeal NPRM gave some examples of these concerns, such as the potential for the definition of significant guidance to be construed broadly, the opaque language in the civil enforcement rule that could result in opportunistic litigation, and the possibility of overwhelming guidance petition obligations. 86 FR 58046, 58049, 58051. Indeed, although HHS stated in the preamble to the final Guidance rule that it believed there would be relatively few significant guidance documents, 85 FR 78775, we no longer think that accurately represents past practice. The risks of these harms—some of which may not yet have materialized—supply additional “good reasons” to eliminate these self-imposed procedural requirements.

Finally, we note that HHS does not need to demonstrate any specific harms, or even risk of harm, in order to justify the repeal of these rules. These rules govern agency procedures, and agencies are generally free to fashion their own rules of procedure in a manner that will maximize the execution of their duties. At most, HHS must show that the decision is permissible under the statute and that there are good reasons for it. *FCC v. Fox TV Stations, Inc.*, 556 U.S. at

515-16. HHS has cited a range of good reasons for this final repeal rule, as noted throughout this preamble. Given that the record for promulgation of these rules contained mainly policy justifications, without citing concrete issues that needed to be solved, HHS does not now believe that it is required to meet a higher burden, cataloging specific facts and examples, in order to justify reversal.

f. Specificity and consistency

One commenter opined that the Repeal NPRM should have identified which existing procedural regulations comply with principles of due notice, fairness, and transparency in order to support HHS's position that the Civil Enforcement rule is not required. The commenter also asserted that HHS's position in the Repeal NPRM was contradictory because the Department both stated that its preexisting regulations provide sufficient fairness and transparency and stated that the Civil Enforcement rule may conflict with the preexisting regulations; the comment stated that the Civil Enforcement rule "cannot simultaneously be coextensive with and in conflict with preexisting enforcement regulations."

HHS believes that all of its preexisting procedural regulations comply with principles of due process, fairness, and transparency, and it is not aware of any information to the contrary. When the Civil Enforcement rule was issued, HHS did not identify any specific deficient processes. In fact, HHS indicated the opposite; for example, it conveyed that existing HHS procedures generally already satisfy the standards in § 1.9. 86 FR 3012. Furthermore, the comments on the Repeal NPRM, including this comment, did not identify specific procedural defects that would be solved through the Civil Enforcement rule. Based on this record, HHS is not aware that any of its preexisting procedures are problematic, and it does not agree that it now has a burden to cite and explain how each of its procedures comport with fairness and due process.

The commenter also misunderstands HHS's position in the Repeal NPRM. HHS does not consider the Civil Enforcement rule and its preexisting regulations "coextensive," but does

consider its preexisting regulations to comply with principles of due notice, fairness, and transparency. The preexisting regulations can comply with these principles without, for example, meeting the specific process laid out in 45 CFR 1.9 of (1) written notice of the initial legal and factual determinations, (2) an opportunity to respond in writing, and (3) a written response from the Department upon request, each of which, under the regulation, must occur “prior” to the Department taking a civil enforcement action.¹⁰ The Civil Enforcement rule itself contemplated that § 1.9 was not mandated by principles of due process; it stated that the process “may exceed the requirements imposed by the Due Process clause of the Constitution and may impose a burden by delaying the time until HHS can take actions with legal consequence.”¹¹ 86 FR 3013. HHS’s processes can vindicate the goals of due notice and fairness through methods other than the prescriptive steps and documentation required under § 1.9, such as engagement through regulatory meetings.

g. Benefit-cost analysis

One commenter stated that HHS failed to fully consider the benefits of the Final Rules and argued that, under the APA, HHS must weigh the costs of the repeal against its benefits. Another commenter stated that the costs of the Guidance rule outweigh its benefits but recommended that HHS summarize those costs and benefits in a designated Regulatory Impact Analysis (RIA) section.

HHS disagrees that the APA requires a benefit-cost analysis such as an RIA for rulemaking in general and more particularly for the procedural rules that are the subject of this rulemaking. We also note that nothing in 5 U.S.C. 301, which provided the statutory authority

¹⁰ The preamble to the Civil Enforcement rule states that the final “written response may be issued contemporaneous to the Department taking the action with legal consequence.” 86 FR 3012. However, HHS is concerned that a court may not find that statement accurate or persuasive in light of the regulatory language itself, which provides that the Department “shall provide” the response “prior” to the civil enforcement action. *See, e.g., Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 53 (D.C. Cir. 1999) (“[L]anguage in the preamble of a regulation is not controlling over the language of the regulation itself.”).

¹¹ The Civil Enforcement rule referred to § 1.6, rather than § 1.9, in this sentence. We now believe this was an error, and was intended to refer to § 1.9, because the rule describes the relevant provision as providing a “process” with “an opportunity to respond in writing before the Department takes an action that has (potentially costly) legal consequence.” 86 FR 3013. Section 1.6 relates to Department reliance on guidance documents and does not establish a process with an opportunity to respond in writing.

for the Final Rules as well as this repeal, requires a benefit-cost analysis. Nevertheless, HHS has considered the advantages and disadvantages of these rules and has determined that they should be repealed. In making this decision, the Department considered the benefits of the rules cited by commenters, which are addressed throughout this preamble. For example, HHS has considered that the Guidance rule requires more process for significant (and other) guidance, which may have the benefit of refining guidance to a greater extent, but also has the disadvantage of delaying, and possibly preventing, the communication of valuable information. With respect to the uniform and mandated disclaimer for guidance, HHS recognizes that there is benefit in acknowledging a document's non-binding nature but has concluded that there is greater harm in requiring one consistent disclaimer across the Department. HHS is also aware that some regulated entities would prefer for all standards and practices to be publicly stated before they are applied in civil enforcement proceedings, but has determined there is greater benefit to the public if the Department is not constrained in taking appropriate actions and positions as circumstances arise. More broadly, overall, HHS believes there is a net negative in establishing these Department-wide procedures by regulation, regardless of the merits of the underlying policies. However, the Department intends to retain some of the policies without the regulations, such as the guidance repository, so the associated benefits will continue. In these and other ways, HHS has balanced the pros and cons, and its determination is both reasonable and well supported.

HHS agrees with the commenter who stated that the harms of the Guidance rule outweigh its benefits. The comment noted that the Guidance rule creates costs in terms forgone health benefits, costs to regulated entities, and increased monitoring burdens on the public. Accordingly, HHS has included an assessment of the impacts of this final repeal rule in the "Required Regulatory Analyses" section, see Section V.A. below.

h. Consideration of alternatives

One commenter proposed various modifications to the rules as an alternative to repeal and questioned whether HHS had adequately justified a repeal of the Final Rules in their entirety in light of these proposed alternatives. The commenter’s proposed modifications include: (1) revising § 1.1 to exempt FDA from the scope of the guidance regulation; (2) revising § 1.2(a) to clarify that the definitions in that section do not apply to FDA to the extent they conflict with FDA’s GGP regulations and that “[d]ifferent definitions may be provided in Federal statutes or regulations that apply more specifically to particular programs or activities;” (3) revising § 1.3(a)(3)(i) to require HHS and each of its components to “prepare a template statement (or multiple template statements,[] . . .) that disclaims any binding effect,” and until they do so, require agency components to include the disclaimer provided in the original § 1.3(a)(3)(i); (4) revising § 1.4(a)(2) to provide that guidance documents not included in the guidance repository will not be considered automatically rescinded upon the Secretary making certain findings, including that the failure to include was inadvertent, or alternatively, eliminating the automatic rescission language altogether; (5) revising § 1.5(d) to permit the Secretary to extend the deadline for the Department’s response to petitions for review of guidance if they “present a complex question that cannot reasonably be responded to within 90 business days,” or adding a third basis for suspension of the deadline; and (6) revising § 1.7(a) to remove the requirement that, in civil enforcement actions, the Department may only apply standards or practices “that have been publicly stated.”

HHS disagrees with the commenter that the commenter’s proposed modifications to the Final Rules are better alternatives to address the concerns with the rules and that these alternatives would obviate the need to repeal the rules in their entirety. As a threshold matter, it is not clear that the Department must consider modifications to these procedural rules prior to rescinding them. Under *State Farm* and *Regents*, “[w]hen an agency rescinds a prior policy its reasoned analysis must consider the ‘alternative[s]’ that are ‘within the ambit of the existing [policy].” *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020) (quoting *State*

Farm, 463 U.S. at 51). Under this standard, an agency must give “adequate reasons for its abandonment” of any such alternatives. *State Farm*, 463 U.S. at 51. However, as explained in Section IV.F.2.a. above, it is not clear that the standards set forth in this precedent apply equally to rules governing agency procedures such as the Final Rules. *See Vt. Yankee*, 435 U.S. at 544 (recognizing agency autonomy to develop its own procedural rules as a “very basic tenet of administrative law”). Moreover, the Department notes that to the extent *State Farm* and *Regents* apply to its decision to repeal these procedural rules in their entirety, those precedents make clear that an agency is “not required to . . . ‘consider all policy alternatives in reaching [its] decision’” and is “not compelled to explore ‘every alternative device and thought conceivable by the mind of man.’” *Regents*, 140 S. Ct. at 1914 (first quoting *State Farm*, 463 U.S. at 51; then quoting *Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 425 U.S. 519, 551 (1978)); *see State Farm*, 463 U.S. at 51 (“Nor do we broadly require an agency to consider all policy alternatives in reaching decision. It is true that a rulemaking cannot be found wanting simply because the agency failed to include every alternative device and thought conceivable by the mind of man regardless of how uncommon or unknown that alternative may have been.”) (internal punctuation omitted).

Nevertheless, to the extent that HHS is required to consider modifications to the existing rules prior to rescinding them, HHS has satisfied that requirement. HHS has considered modifications to the Final Rules, including the commenter’s proposed modifications, and has determined that any such modifications are not better than repeal for several reasons.

As explained in previous comment responses and elsewhere throughout this preamble, HHS has determined that codifying the practices and procedures set forth in the Final Rules, even if modified as the commenter suggests, is not necessary or appropriate for several reasons. As noted previously in the Repeal NPRM, neither of the Final Rules required notice-and-comment rulemaking before promulgation. *See* 86 FR 58045-46. Moreover, the Department does not find it appropriate to codify these practices and procedures regarding guidance and civil

enforcement because doing so would inhibit the ability of HHS agencies to update and revise these practices and procedures as needed over time in response to a variety of factors, including changed circumstances, new priorities, public health emergencies, stakeholder input, new technology, changes in applicable legal precedent, and agency experience. Such revisions would be generally time-consuming and resource-intensive if these practices and procedures remained codified in a regulation. HHS does not believe that its finite resources are best used to undertake such efforts, especially given the limited utility of the Final Rules. The Department's desire to retain flexibility to modify practices and procedures regarding guidance and civil enforcement is consistent with Congress's objective that the APA should allow "agencies . . . latitude in organizing their internal operations," *Mendoza v. Perez*, 754 F.3d 1002, 1023 (D.C. Cir. 2014) (internal quotation marks omitted) (recognizing this principle as a ground for Congress's exemption of agency procedural rules from the requirement to conduct notice-and-comment rulemaking); *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987) ("The reading of the [section] 553 exemptions that seems most consonant with Congress' purposes in adopting the APA is to construe them as an attempt to preserve agency flexibility in dealing with limited situations where substantive rights are not at stake."); *see also* *Vt. Yankee*, 435 U.S. at 544 ("agencies should be free to fashion their own rules of procedure").

Additionally, HHS has determined that codifying the Final Rules or any modification of them is not appropriate because implementing a one-size-fits-all approach to the practices and procedures regarding guidance and civil enforcement cannot accommodate the needs of the diverse range of HHS agencies. As explained in Section IV.A.4.b above, each of the HHS agencies serves the Department's overall mission in unique ways, often addresses different stakeholders, uses specialized regulatory tools and existing processes for guidance and civil enforcement, and is subject to unique statutory authorities. To develop practices and procedures applicable to and appropriate for all HHS agencies, the Department would need to consider and accommodate these different stakeholders, tools, existing processes, and statutory authorities.

The Department now believes that the Final Rules did not adequately address this issue. Even assuming it would be possible or practical for the Department to do so in the context of a single rulemaking, the Department does not find it appropriate to commit its limited resources to such a time-consuming and resource-intensive task. Although the commenter's proposal to exempt FDA from the Guidance rule addresses some of these concerns for one agency and one rule (the commenter does not propose to exempt FDA from the civil enforcement rule), that approach does not address the unique considerations presented by each of the other HHS agencies.

HHS has determined that the commenter's proposed modifications to the Final Rules are not preferable to repeal for other reasons, as well, including that they do not address the Department's following additional concerns regarding such provisions.

First, the commenter's proposal to revise § 1.2(a)—to exempt FDA from its definition of “guidance document” and acknowledge that “[d]ifferent definitions may be found in Federal statutes” but retain the rule's original “guidance document” definition—does not adequately address the Department's concerns that the “guidance document” definition is vague and overly broad, could lead to confusion over the type of documents subject to the rule's requirements, and could be read to encompass a range of documents not intended to serve as guidance. The commenter asserts that the definition is not vague or confusing because it is consistent with the APA's definition of a rule as well as “definitions that have long been used by courts and agencies to define the categories of agency documents that are properly considered guidance.” Moreover, the commenter suggests that any difficulty in interpreting § 1.2(a)'s definition of guidance is not attributable to that section's language but “inheres in the nature of [defining] agency guidance,” which courts have described as “‘fuzzy’ and ‘enshrouded in considerable smog,’” and that “to the extent the Department believes further clarification is needed to explain how the definition of guidance applies to specific documents, it should provide clarity through further preamble guidance explicating how HHS understands this term.”

However, as discussed in the Section IV.F.2.c. above, the nuanced nature of determining

whether an agency document constitutes guidance counsels against attempting to reduce the relevant legal principles to regulatory language and makes it difficult for the Department to ensure that any regulatory definition fully captures the context and meaning of relevant court decisions. Furthermore, the Department does not agree with the commenter's assertion that § 1.2(a)'s definition ameliorates difficulty in identifying agency guidance documents by "adding clarifications that discuss specifically how HHS documents are likely to fit or not fit within the definition." The Department sees limited value in the examples provided in the definition, which primarily include legislative rules and documents that clearly fall outside the definition of guidance, *see, e.g.*, 45 CFR 1.2(a) (providing that "guidance documents" do not include "rules promulgated pursuant to notice and comment under 5 U.S.C. 553," "decisions of agency adjudication under 5 U.S.C. 554," "legal briefs and other court filings," "grant solicitations and awards," and "contract solicitations and awards"), or essentially reiterate the legal principles already incorporated into the general definition, *see id.* (providing "guidance document" does not include "internal guidance directed to the Department or other agencies" *but* would include such documents if they were "intended to have substantial future effect on the behavior of regulated parties"); *see also id.* (excluding from the definition of "guidance document" various "[p]re-enforcement rulings" *but* acknowledging that "[i]f, however, . . . the content of the document is designed to guide the conduct of other regulated parties, such a document would qualify as guidance").

Second, the commenter's proposed revisions to § 1.3(a)(3)(i)—to require HHS and each of its agencies to individually "prepare a template statement (or multiple template statements,[] . . .) that disclaims any binding effect," but until they do so, require them to use the disclaimer provided in the original § 1.3(a)(3)(i)—are not a better alternative to rescission of this section in its entirety. Although requiring each HHS agency to develop its own templates for guidance documents represents an improvement on the rule's original requirement that a uniform statement be used for all Department documents, it is not clear that this approach would provide

each agency with enough flexibility to specify the information most appropriate to each HHS agency's stakeholders and the expected uses of each particular document or type of document. As discussed in Section IV.D.4. above, the Department believes that a flexible approach is preferable so that each HHS agency can develop an approach to help ensure that the statement is as clear and useful as possible, informed by the unique considerations applicable to that agency and using the regulatory tools it deems best suited to the task. Although FDA's GGP regulation contains a requirement cited by the commenter as a model, neither the FD&C Act nor FDA's GGP regulation codify the wording of the disclaimer statement; rather they broadly require that FDA guidance documents indicate the non-binding nature of the document. *See* 21 U.S.C. 371(h)(2) and 21 CFR 10.115(i)(1)(iv). The Department does not find it necessary or appropriate to promulgate a regulatory requirement that all agency components undertake such an effort, given the numerous demands on the Department's finite resources, the unique considerations presented by the various guidance documents issued by each of the Department's components, and existing law establishing the non-binding effect of guidance documents regardless of inclusion of a disclaimer of legal effect.

Additionally, the Department rejects the commenter's proposal to require HHS agencies, pending their adoption of a template, to include in all guidance documents § 1.3(a)(3)(i)'s original disclaimer statement, given the Department's determination that the original disclaimer statement is not appropriate for inclusion across the diverse range of guidance documents issued by agency components. The commenter asserts that the rule's original disclaimer statement is an appropriate fit for all Department guidance documents because it "accurately and clearly restates core principles of administrative rulemaking applicable to all agencies," namely, that "guidance may not carry 'the force and effect of law.'" However, as explained in Section IV.D.4. above, the Department sees little utility in issuing a regulation to require a disclaimer that simply seeks to capture a current understanding of principles established by the APA, and any attempt to do so incurs the risk of confusion to the extent that the language does not fully capture the context and

meaning of relevant court decisions.

Third, the commenter's proposed revisions to § 1.4(a)(2)—to provide that guidance documents not included in the guidance repository will not be considered automatically rescinded if the Secretary makes certain findings—also does not present an adequate alternative. This proposed process for averting or reversing inadvertent rescissions would create additional burdens for the Department because it would require the Secretary to make specific, narrow and undefined findings about each rescission that: “[t]he guidance document was omitted from the guidance repository inadvertently due to a technological or human error;” “[r]egulated parties had fair notice of the guidance document during the period it did not appear in the guidance repository;” and “[t]he guidance document was added to the guidance repository promptly after the Department learned of its inadvertent omission.” Moreover, providing the possibility that the Secretary could proactively prevent rescission by making certain findings will not prevent automatic rescission from happening inadvertently. And, as discussed in Section IV.D.5, automatic rescission due to inadvertent exclusion would create additional burdens on stakeholders by causing unnecessary confusion about which guidance documents have been rescinded, superseded, or otherwise become obsolete. Furthermore, this proposed alternative for reinstating automatically rescinded guidance would likely exacerbate stakeholder confusion because the effectiveness of guidance could flip back and forth depending on technical glitches with the website and whether the Secretary has been able to address them.

The commenter proposed, as an alternative revision to § 1.4, to retain § 1.4's requirement to establish and maintain a guidance document repository but provide that failure to include a guidance document in the repository would not be grounds for treating the guidance document as rescinded. We agree with the proposal to maintain a centralized repository and eliminate the automatic rescission provision. However, we conclude that it is unnecessary and unhelpful to retain the codified regulation. Removing the automatic rescission language in § 1.4 would leave only the requirement that the Department maintain the guidance repository along with certain

specifications for the repository. As discussed in Section IV.D.5, the Department intends to retain the guidance repository and to improve the utility of the repository based on stakeholders' input and other developments, such as new technology. We see no benefit in directing the Department's efforts with a codified regulation.

Fourth, the commenter's proposed revisions to § 1.5(d) are also not a preferable alternative to rescission. Although permitting the Secretary to extend the deadline for the Department's responses to petitions that present a "complex question that cannot reasonably be responded to within 90 business days," or adding additional bases for tolling the deadline, may in some ways alleviate the Department's concerns regarding its ability to respond to such petitions in such a short timeframe, these proposed mitigation measures do not sufficiently address the unnecessary diversion of resources to this new petition pathway. The commenter does not address the Department's concerns regarding the other ways in which § 1.5 is likely to strain unnecessarily the Department's resources, as discussed in Section IV.D.6., by, for example, permitting stakeholders to file, and requiring the Department to timely respond to, an indefinite number of petitions, each of which could challenge any number of guidance documents at a time or challenge the same guidance document multiple times. Furthermore, requiring the Secretary to make determinations regarding whether individual petitions present a "complex question" and whether the Department "cannot reasonably . . . respond[] . . . within 90 business days," or whether a basis for tolling exists, would create an additional burden on the Department's finite resources.

Moreover, the commenter does not explain why such burdens would be justified, given the existence of other formal and informal processes by which stakeholders can communicate their views on guidance to the Department. Although the commenter asserts that these processes are not an "equally effective and comprehensive alternative" to § 1.5's petition process and that FDA's citizen petition process is "largely inadequate," it does not provide persuasive support for such assertions. Nor does the commenter support the underlying premise that petitions regarding

guidance documents should be provided a special pathway and be prioritized above other petitions as well the Department's other work. In any event, HHS need not show that the existing processes that it chooses to rely upon in the alternative are "equally effective" or "comprehensive;" rather, at most, HHS need only show that there are good reasons for abandoning § 1.5's petition process and that it believes doing so is the better approach, which it has done here. *See FCC v. Fox TV Stations, Inc.*, 556 U.S. at 515-16 (to justify a repeal, an agency needs to adequately explain why the new policy is permissible under the statute and that there are good reasons for its new position).

Finally, the commenter's proposed modification to § 1.7(a)—to remove the requirement that in civil enforcement actions the Department may only apply standards or practices "that have been publicly stated"—is also inadequate compared to rescission because it addresses only one aspect of the Civil Enforcement rule. Although the commenter's proposal would remove a restriction on the Department's authority that goes beyond settled case law, *see* Section IV.F.2.c; 86 FR 58050, that limited change would not address the Department's concerns regarding other provisions of the Civil Enforcement rule. *See* Section IV.E (concerns with the Civil Enforcement rule include that the newly required procedures do not adequately account for pre-existing, agency-specific procedures regarding civil enforcement actions, may conflict with or diverge from such existing procedures, may create confusion for both HHS agencies and regulated parties, and could create unnecessary burdens that delay or prevent civil enforcement). Although the commenter asserts that the burdens the Civil Enforcement rule imposes on the Department, identified in the Repeal NPRM, are either speculative or justified by the rule's benefits, the Department disagrees. *See* Section IV.E. Moreover, the proposed revision to § 1.7(a) does not address the Department's position that the Civil Enforcement rule, including the portion of § 1.7(a) that would remain under the commenter's proposal (i.e., a prohibition on standards or practices that "cause unfair surprise"), is superfluous because the procedural regulations already established within HHS comply with principles of due notice, fairness, and

transparency. Contrary to the commenter's suggestion that rescission of the rule will "allow[] [the Department] to proceed with enforcement actions that cause unfair surprise" and impose "burdens . . . on regulated entities who are on the receiving end of such enforcement actions," the Department's current procedures already ensure that the procedural rights of stakeholders are adequately protected.

In sum, to the extent that the Department must consider potential modifications to the Guidance and Civil Enforcement rules as alternatives to their rescission, the Department has satisfied any obligation to do so by addressing the modifications proposed in the comments and providing adequate reasons for their rejection. *See State Farm*, 463 U.S. at 51.

i. Reliance interests

One commenter asserted that HHS's consideration of reliance interests in the Repeal NPRM rule was inadequate. The commenter stated that HHS assumed there were no reliance interests due to the revocation of Executive Orders 13891 and 13892 and that "a change in administration cannot extinguish reliance interests." Another commenter asserted that "reliance interests are serious and ongoing." The commenter questioned HHS's belief that no serious reliance interests have accrued because, in the commenter's view, that belief was contradicted by HHS's assertion that the guidance processes were overly burdensome and resource intensive for the Department.

HHS disagrees that its analysis of reliance interests in the proposed rule was inadequate, and we have reiterated and built on that analysis in this final repeal rule. Consistent with *DHS v. Regents of the Univ. of Cal.*, HHS has considered whether there are significant reliance interests and has weighed those reliance interests against competing policy concerns. 140 S. Ct. 1891 (2020). For example, in the preamble to the proposed rule, HHS gave reasons why it did not believe significant reliance interests have accrued but also communicated the view that, to the extent that any serious reliance interests are at stake, they are outweighed by the public interest in efficient issuance of guidance and adequate civil administrative enforcement actions. Thus,

HHS stated that it was unlikely that reliance interests had accrued, but also acknowledged the possibility of reliance interests and weighed them against relevant policy considerations.

HHS has not changed its analysis of reliance interests. Although one comment stated that reliance interests are “serious and ongoing,” the commenter based that view on the Department’s statement that the Final Rules are burdensome and resource intensive. While it is true that the Final Rules are resource-intensive in part because the public has used the processes (for example, the guidance petition process), that fact does not mean that the public has developed reliance interests. Reliance interests generally accrue through decisions made in reliance on the prior policy, such as decisions to have “enrolled in degree programs, embarked on careers, started businesses, purchased homes, and even married and had children,” *Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. at 1914, or business “investment[s] incurred,” *Solenex LLC v. Bernhardt*, 962 F.3d 520, 529 (D.C. Cir. 2020) (internal quotations omitted).

HHS does not believe that the public has made these types of decisions based on the Final Rules. As noted in the proposed rule and throughout this preamble, these rules govern agency procedures, so they do not on their own change the substantive requirements governing regulated entities or related property interests. Thus, it is difficult to see how the procedures or principles set forth in these rules would translate to a stakeholder making concrete changes in public or business decisions or practices that would implicate serious reliance interests.

In considering reliance, HHS also has not taken the position that a change in Administration extinguishes reliance interests. Under the facts here, the timing of the change in Administration is relevant because the Final Rules were issued at the tail end of the last Administration, and the Biden-Harris Administration immediately revoked the Executive orders that formed a key basis for the rules (EOs 13891 and 13892). Accordingly, the Final Rules were effective for only a few days or weeks before the public was put on notice that there was a change in the underlying policy. At that point, even if we were to assume for argument’s sake that reliance interests accrued, the public was less likely to invest significant resources in

reliance on the rules. Given that the public had little time to develop reliance interests before the change in Administration and had little reason to develop those interests after the change, in combination with the points made above, HHS does not believe that serious reliance interests have accrued.

To test its view, HHS invited the public to provide information about reliance interests adversely affected by the repeal. Other than the commenters discussed above, we did not receive any responses on this topic. No commenters provided specific examples of affected reliance interests. Instead, HHS received multiple comments discussing reliance on government programs involving guidance and stating that the Guidance rule itself undermines those interests. These facts corroborate and reinforce our analysis of reliance interests. In sum, HHS has considered whether significant reliance interests exist and has weighed those against its policy goals, and therefore has met its burden under the APA.

V. Required Regulatory Analyses

A. Executive Orders 12866 and 13563

We have examined the impacts of the final repeal rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this final repeal rule is a significant regulatory action as defined by Executive Order 12866. This is consistent with the Repeal NPRM, which OMB found to be a significant regulatory action.

In both the Guidance proposed and final rules, OMB determined that the rulemaking was not an economically significant regulatory action under these EOs. 85 FR 51399; 85 FR 78784. OMB made a similar finding with respect to the Civil Enforcement rule. 86 FR 3013. The

preambles to these rules maintained that the rules primarily described procedural changes that would require Department expenditures to implement. Although the preambles theorized that stakeholders might eventually benefit from greater transparencies and efficiencies from these procedural changes, the Final Rules did not identify any benefits that were likely to be immediately realized. *See* 85 FR 78784; 86 FR 3013.

In the current rulemaking, the Department is repealing the Final Rules, which were effective on January 6, 2021, and January 12, 2021. When effective, this repeal rule will restore the status quo that existed just prior to the January 2021 effective dates for the Final Rules. The Department may then take further action as needed to undo any minimal actions taken since those effective dates to implement the rules' procedural directives.

Compared to the baseline scenario under the rules on guidance, enforcement, and adjudication procedures, we identify several impacts of the final repeal rule. We anticipate that the final repeal rule will result in: reduced costs to the Department to administer the Department's programs; reduced costs associated with litigating internal procedures; and reduced costs associated with responding to citizen petitions purported to be submitted under the Guidance rule. The sum of these cost savings attributable to the final repeal rule are very unlikely to exceed the \$100 million threshold in any year. As an additional impact, we anticipate that the final repeal rule will result in benefits from reduced regulatory confusion, such as confusion from two sets of regulations governing FDA guidance practices, citizen petitions related to FDA guidance, and CMP proceedings.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$165 million, using the most current (2021) Implicit Price Deflator for the Gross

Domestic Product. This final repeal rule would not result in an unfunded mandate in any year that meets or exceeds this amount.

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), OIRA has determined that this final repeal rule is not a “major rule” as defined by 5 U.S.C. 804(2).

B. Regulatory Flexibility Act

The Department has examined the economic implications of this final repeal rule as required by the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.* The RFA and the Small Business Regulatory Enforcement and Fairness Act of 1996 (Pub. L. 104–121), which amended the RFA, require HHS to analyze options for regulatory relief of small businesses. If a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule. The Department considers a rule to have a significant economic impact on a substantial number of small entities if it has at least a three percent impact on revenue of at least five percent of small entities.

When finalized, this repeal rule will restore the status quo just prior to the respective January 6, 2021, and January 12, 2021, effective dates of the Guidance rule and the Civil Enforcement rule, and undo changes, if any, to procedures followed by the Department during the interim period. This rule repeals two rules that the Department concluded, and the Secretary certified, would not result in a significant impact on a substantial number of small entities. Further, the Department believes that any effects associated with future regulatory actions, including any positive or negative impacts to small entities, should be attributable to those regulatory actions rather than to this repeal rule. As a result, the Department has determined, and the Secretary certifies, that this final repeal rule does not have a significant economic impact on the operations of a substantial number of small entities.

C. Executive Order 13132 (Federalism)

We have analyzed this final repeal rule in accordance with the principles set forth in EO

13132, “Federalism.” The Department has determined that this final repeal rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

D. Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments)

HHS has analyzed this final repeal rule under Executive Order 13175, dated November 6, 2000, and has determined that this action does not have tribal implications as specified therein. This final repeal rule would not impose any direct compliance requirements on Indian tribal governments and will not have any economic or other impacts on the viability of Indian tribes. Therefore, a tribal summary impact statement is not required.

E. National Environmental Policy Act

HHS had determined that this final repeal rule will not have a significant impact on the environment. Because the Final Rules that are being repealed established only procedures related to issuing guidance and initiating civil enforcement, this repeal is not a major Federal action significantly affecting the quality of the human environment within the meaning of NEPA.

F. Paperwork Reduction Act of 1995

In accordance with the Paperwork Reduction Act of 1995 and its implementing regulations, 44 U.S.C. 3501–3521; 5 CFR part 1320, appendix A.1, the Department has reviewed this final repeal rule and has determined that it does not create new collections of information.

List of Subjects in 45 CFR Part 1

Government employees, Guidance, Reporting and recordkeeping requirements.

PART 1 – [REMOVED AND RESERVED]

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR, subtitle A, subchapter A, by removing and reserving part 1.

Dated: July 18, 2022.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

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